No. 2013-1445

IN THE
United States Court of Appeals
FOR THE FEDERAL CIRCUIT

DATCARD SYSTEMS, INC.,

Plaintiff-Appellant,

v.

PACSGEAR, INC.,

Defendant-Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA IN
CASE NO. 10-CV-1288, SENIOR JUDGE MARIANA R. PFAELZER

NONCONFIDENTIAL JOINT APPENDIX
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Confidential information of Pacsgear, Inc. has been deleted from this appendix. The confidential information generally relates to: (a) the functionality of the accused Pacsgear MediaWriter product, and (b) the release dates of certain MediaWriter upgrades.

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FOR THE CENTRAL DISTRICT OF CALIFORNIA
SOUTHERN DIVISION

DATCARD SYSTEMS, INC., a California corporation, Plaintiff, v. PACSGEAR, INC., a California corporation, Defendant. AND RELATED COUNTERCLAIM	Civil Action No. SACV10-1288 DOC (VBKx) **INITIAL EXPERT REPORT OF DR. ALAN ROWBERG, M.D.**

CONFIDENTIAL ATTORNEYS' EYES ONLY

CONFIDENTIAL MATERIAL OMITTED PURSUANT TO PROTECTIVE ORDER

A1963, A1964, A1965, A1966, A1967, A1968, A1969, A1970, A1971

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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

DATCARD SYSTEMS, INC., a California corporation Plaintiff, v. PACSGEAR, INC., a California corporation Defendant.	Case No. SACV 10-1288 DOC (VBKx) **PACSGEAR INC.'S MEMORANDUM IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT OF <u>NON-INFRINGEMENT</u> OF THE "SEARCH/BURN PATENTS"**
PACSGEAR, INC., a California corporation, Counter-Claimant, v. DATCARD SYSTEMS, INC., a California corporation, Counter-Defendant.	Hearing Date: February 13, 2012 Hearing Time: 8:30 a.m Courtroom of Judge Carter Discovery Cut-Off: Dec. 23, 2011 Trial Date: April 17, 2012

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I. OVERVIEW

PacsGear seeks summary judgment of non-infringement as to all claims that its MediaWriter product does not infringe three of the five patents in suit: U.S. Patents Nos.,7,302,164 B2, reissued without substantial change as the 7,302,164C1, and its two offspring 7,729, 597 and 7,783,174. We refer to these as the Search/Burn patents because they all claim a system and method for searching for medical images on a DICOM conforming PACS system, and burning the images onto a compact disc. DICOM is the standard for taking images from modalities (X-Rays, MRI's etc.), storing them and making them searchable by doctors. DICOM-compliant PACS are systems which convert medical images derived from various modalities into the standard format (DICOM), thereby permitting easy and cost-effective storage, search, transmission, viewing and copying. See PacsGear Reports and Deposition Excerpts, Ex. A, Horii Initial Report, ("Horii I"), pp. 9-11.

PacsGear does not include the '157 "HIPAA" patent in this motion because it believes that keeping an electronic record of CD's carrying patient information cannot be patentable, in part because it is essentially illegal not to have an audit trail. It is filing a separate MSJ for invalidity and non-infringement of the '422 patent, because that patent centers on a technical issue of software programming, calling for a different skill in the art.

This motion discusses only the independent claims, because if PacsGear does not infringe those, it cannot infringe their dependent claims.

Some of the claims are method claims. Generally, plaintiff does not allege that PacsGear directly infringes such claims, but rather that its customers infringe them in the manner that they use them. We analyze them from the customers' perspective because if they do not infringe, then PacsGear cannot be liable for contributory infringement or inducing infringement.

For ease of reference, we attach the complete '164 patent as Appendix A, followed by the claims of each patent in readable type size, with the limitations numbered as Appendices B-D. The central issue with all three patents is the meaning to be giving to the

distinction between data "selected" by the user, and "related" data which is somehow "automatically" generated in response to the users selection, regardless of whether the user wants it. Depending on the construction of these terms, the Search/Burn claims are either invalid and/or are not infringed, and occasionally both.

II. DESCRIPTION OF THE MEDIA WRITER

PacsGear's MediaWriter is a PACS accessory called a medical disk publishing device. It consists of a computer with a single monitor, a CD/DVD burning device and software which enables a user to select medical image studies[1] from a hospital's DICOM-conforming PACS image database and burn them onto a CD along with viewing software so they can be read by any computer. The dialog box below shows how a user can select specific studies:

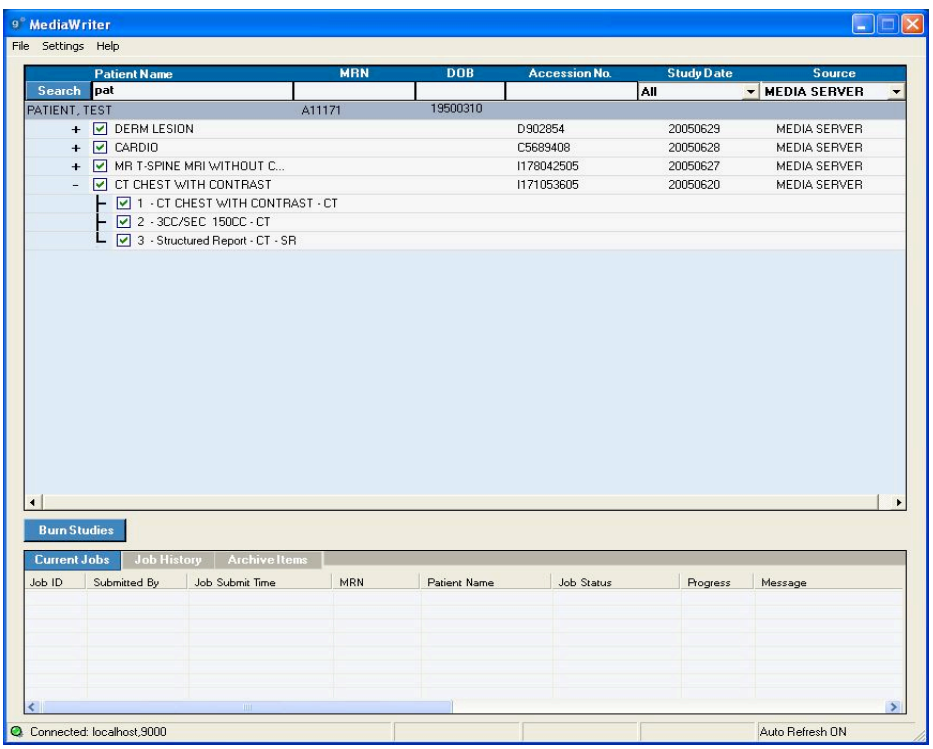


FIGURE 1

[1] A "study" is the term of art for the image or images taken by a modality in a single exam, whether it be one image (X-Ray) or hundreds (heart catheterization procedure). "Reports" are text data, such as diagnostic reports.

The MediaWriter does not conduct an automatic secondary search for images related to the selected images. In other words, the only *images* that can be burned on to the CD are those that are expressly selected by the user, using the dialog box as shown.

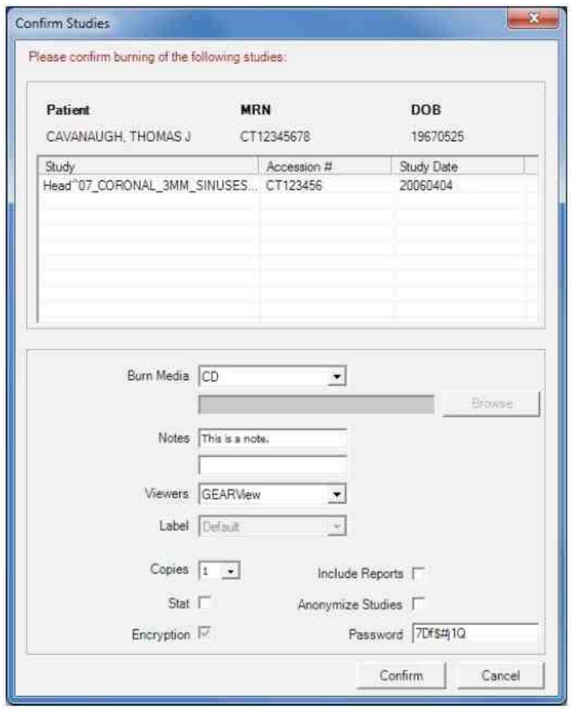
Starting with MediaWriter version 3.0, PacsGear added a feature to the software that allows the user to burn the radiologist's text reports interpreting the selected images onto the CD along with the selected images. ("Configure Reports Option", Ex. 217, User's Manual, p. 24-25).

The user of the MediaWriter and/or PacsGear, based on the customer's request, must specifically configure the MediaWriter software to search for these text reports, namely reports received by the MediaWriter via an HL7[2] feed or from a DICOM compliant archive, namely a PACS broker. This feature, however, does not allow the user to conduct a search for image studies. See Ex. 258, Cavanaugh Dec., ¶¶2-17. These reports can be stored in a distinct folder on the hard drive of the MediaWriter or on a PACS broker, sometimes referred to as a MitraBroker, designed to store text reports. These reports are in text format and are not DICOM images.

Several steps are necessary for the MediaWriter to burn medical images onto a CD. First, the user inputs the patient's name and is shown a menu of studies. He/she then selects all the image studies he/she wants to burn by moving a cursor to a box preceding each entry of the listed studies and clicking the computer's mouse, and then positioning the cursor over the Burn Studies button and clicking the computer's mouse (i.e., hitting the Burn Studies button on the dialog box above). After clicking on the computer's mouse to hit the Burn Studies button, a Confirm Studies dialog box pops up (see below), which allows the user to make additional choices, including whether to include text reports. If text reports are desired AND the system has been previously configured to obtain such text reports, the user can check the "Include Reports" box and then click on the "Confirm"

[2] HL7 ("Health Level 7") is the communication protocol used by a hospital to distribute written information from its Radiological Information System (RIS). The HL7 protocol sends diagnostic reports from the RIS to devices configured to receive them.

button and the images originating from the (DICOM) image database and the text reports from a separate location are burned onto a CD along with a viewing program. The CDs are automatically labeled with identifying information drawn from the patient demographics and relevant studies. (Ex. 217, User's Manual, pp. 24-25).



The MediaWriter processes HL7 or Mitra broker reports for all relevant purposes, in essentially the same way as the prior art system installed at UCLA in 1998-99 and described in the Ratib Article, (Ex. 148 in the Exhibit book) and Declaration (¶¶9-16). Other features of the MediaWriter will be discussed as they pertain to specific claims.

III. THE MEDIA WRITER DOES NOT INFRINGE THE '164 PATENT[3]

A. Claim Construction Of Claim 9

1. Claim construction Principles

The court must interpret the claims as a matter of law before determining validity or infringement. Markman v. Westview Inst., Inc., 52 F.3d 967 (Fed.Cir. 1995), aff'd, 517 U.S. 370, 116 S.Ct. 1384 (1996). Where one patent is a continuation from the same application as another, construction of terminology common to them should be the same for both patents. Abtox, Inc. v. Exitron Corp., 122 F.3d 1019 (Fed.Cir. 1997). Where terms have been given no special meaning by the inventor, they are to be interpreted according to how one with ordinary skill in the art would read them. Hockerson-Halberstadt, Inc. v. Avia Group Int'l., 222 F.3d 951, 955 (Fed.Cir. 2000). Ambiguous terms are to be interpreted under a hierarchy of evidence, the claims, the specification, then the file history, and, if still ambiguous, to extrinsic evidence. (Markman at 979-980).

2. Person having ordinary skill in the art

PacsGear's medical image expert Dr. Horii discusses the need for the person of ordinary skill in the art (PHOSITA) to blend knowledge of digital information systems and DICOM imaging technology in the medical field. He has a unique background for that task in that he was on the committee that drafted the initial examination for Certified Informatics Information Professionals ("CIIPs"), implemented in 2007. CIIP's have training and experience in digital information technology and imaging modalities as they relate to DICOM. Dr. Horii's profile of the hypothetical person of skill is a CIIP, had that title existed at the time of the patent filing, with five years experience in the design, use and implementation of PACS or a radiologist or medical computer networking specialist with equivalent experience. (Ex. A, Horii I, pp. 8-9).

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[3] For convenience, the '164 Patent is attached as Appendix A, hereto. The Claims in a more readable format are attached as Appendix B ('164), Appendix C ('597 Patent) and Appendix D ('174 Patent).

Inventor Ken Wright's profile of the PHOSITA is extremely similar. He posits someone who would "at least need to be certified with some sort of medical schooling or medical background…" and "who would need to understand the business of radiology or information systems, training enough to understand DICOM and how the inner working parts work" with "three or four years of experience." (Ex. I, Wright Dep., pp. 233-34).

Plaintiff's PACS expert Dr. Rowberg's profile is a person with a bachelor's degree in science or engineering with a year of work experience, or a person with 3 years of work experience. (Rowberg Initial Report, Ex. C, pp. 14-15 ("Rowberg I")). Since he does not state whether the work experience has to have anything to do with radiology, medicine, computer programming or hospitals—Dr. Rowberg's profile is inadequate.

3. The first three limitations

The first three limitations in Claim 9[4] provide for a medical image server configured to receive medical images from a plurality of—at least two-- modalities, e.g. MRI's and X-rays—in a "standard medical imaging format"—i.e., DICOM—viewable on computers capable of viewing DICOM images.

The second provides for "a database" configured to store medical images generated by plural modalities. Necessarily, this database must store images in DICOM format,

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[4] 9. A system comprising:

[1] medical image server configured to receive medical image data that is generated by a plurality of imaging modalities, the medical image data being formatted in a standard medical imaging format used by specialized computers configured for viewing medical images;

[2] a database configured to store medical image data generated by the plurality of imaging modalities;

[3] a plurality of browsing terminals configured to receive a user selection that defines selected medical image data;

[4] a search module configured to search the database for related medical image data that is related to the selected medical image data; and

[5] a production station that is configured to record all of the following onto a single, portable digital data storage device that is removable from the production station: the selected medical image data, recorded in the standard medical imaging format, the related medical image data, recorded in the standard medical imaging format, and a viewing program that is configured to allow viewing of the selected and the related medical image data that is recorded onto the data storage device on widely accessible computers not specifically configured with standard medical imaging software for viewing of medical images.

because the images it receives must be in DICOM format according to the first limitation. It also must be searchable as a user searches it to retrieve the selected images.

The third requires a "plurality" of "browsing terminals," computers or dumb terminals with a browser configured to receive "a user selection that defines "selected medical image data." This merely means that users on separate computers/terminals, are able to enter search terms defining the medical image studies data they wish to view.

4. Limitation 4: "Search" of "the database" for "related medical image data"

a. Doctor Horii's construction

The fourth limitation calls for a "a search module *configured to search the database* for *related medical image data* that is related to the selected medical image data."

Dr. Horii reads "related medical image data" to mean digital medical images in DICOM format that are somehow related to the images initially selected by the user—such as earlier studies of the same patient, or, if the user selected a patient's MRI, perhaps a CATScan of that patient. (Horii I, Ex. A, pp. 12-13).

Horii explicitly excludes text reports, based on the "standard medical imaging format", the parallel claim language terms, "selected medical image data" and "related medical image data" as well as the examples in the specification consisting only of medical images. Horii I, pp. 12-13. He reads "the database" to refer back to the same database called for in the second limitation…." He states "…the system is capable of searching the same database in which it found the selected medical images for additional medical images related to the selected medical images." (Ex. B, Horii Rebuttal Report ("Horii II"), p. 8).

He also opines that "database" in the context of claim 9 and according to the conventional technical definition "to mean the electronic collection of image data stored in a way to allow for easy search and retrieval following the request of a user." (Ex. B, Horii II, p. 7). That is, the database must be searchable.

b. Dr. Rowberg's construction as modified in his deposition

(1) related medical image data

In his infringement report, but not in his testimony, Dr. Rowberg disagrees with Dr. Horii on the issue of whether text data—non-image data--is encompassed by "related medical image data."

In his 103-page infringement report Rowberg does not separately construe the claims, but instead implicitly adopts his own construction in his itemized infringement charts. (Rowberg I, Ex. C). He does not reference other limitations, other claims or the specification, and performs no other analysis of the claim terms. His construction must be ferreted out from his invalidity and infringement reports. Thus, in connection with the fourth limitation, he proclaims that the Media Writer meets the limitation because, he says, it can be configured to copy *written reports* to the CD.[5] Rowberg explains away the "related medical image" language by saying it includes text reports "related" to the "selected medical image data," instead of the obvious literal meaning, medical *image* data that is related to the selected medical *image* data. Under his construction, while, the selected medical image data is restricted to image data, the related medical image data need not be.

At his deposition Dr. Rowberg was asked to find any reference to written reports in the specification. (Ex. J, Rowberg p. 46). After an embarrassingly long period, he could not find one. Finally he pointed to a sentence using the term "medical exam data" which Rowberg contended meant written reports. (Ex. I, Rowberg Dep. p. 52). But, he retreated from that statement, too, admitting that in context and based on the specification it was used *as a synonym for medical images*. (Rowberg Dep. p. 56-57). The word "exam" is employed a few times in the specification and each time it specifically refers to images.

[5] "In my opinion, the term 'related medical image data' includes data related to a medical image. Reports originating from HL7 feeds, Mitra broker reports and DICOM structured reports comprise data that is related to a medical image. Thus, it is my opinion that these items constitute 'related medical image data' within the meaning of [limitation 4]." Ex. C, Rowberg Infringement Report, p. 22:20-23.

See, specification Appendix A, hereto, Col. 8:10-35. (e.g., See also Figure 5 of the '164 Patent). Finally, he admitted that "related medical image data" in limitation 4, just like its antecedents "selected medical image data" in limitation 3 and "medical image data" in limitation 2 referred only to medical images. (Ex. J, Rowberg Dep. p. 123 ll. 8-12):

Q. "So one skilled in the art seeing "image data" would think that it only meant---it only referred to images to the exclusion of other things, correct?

A. Yes."

Additionally, according to the inventor, Mr. Wright, in 1999, PACS only stored DICOM images and it wasn't until the 2005/2006 time period that a few PACS manufacturers began allowing anything but images to be stored. (Ex. I. Wright Dep. p. 149). Since at the time of the invention, PACS only stored images, one skilled in the art at the time the application was filed in January, 2001 would have interpreted "related medical image data," in the '164 patent to mean images only.

If Rowberg's admission were insufficient, the fifth limitation puts an end to DatCard's contention that text reports are included within related medical image data. It calls for a CD burner or analogous "production station" configured to download the "selected" *and* "related medical image data", *both* recorded in the "standard medical imaging format." As we have seen, HL7, Mitra reports and any other reports the MediaWriter is configured to collect are in text format, not DICOM. The requirement that related data be in the standard medical imaging format is the final proof that the data in "related medical image data" must consist solely of images.[6] Additionally this limitation requires the viewing software burned onto the CD to be capable of viewing the "selected and related image data." The eFilm viewing software, identified in the patent specification, could only view images and could not read text reports. (Ex. I, Wright Dep. p. 156:7-9).

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[6] One of the inventors, Ken Wright, was involved with HL7 projects from 1992-1999. (Wright Dep. 20:12-20) If he had intended for the patent to cover HL7 reports, he surely would have included it in the specification.

(2) "search" for related data in "the database"

In connection with the term in limitation 4, "search module configured to search the database for related medical image data," Rowberg's report states that this claim is satisfied where the search module searches a different database than the database referred to in limitation 2. (Rowberg Infringement Rpt. Ex. C, p. 23). This was in the context of trying to make claim 9 read on items retrieved in connection with the Configure Reports option (e.g., HL7 fed and Mitra broker reports), which can be stored separately on the MediaWriter's hard drive, in order to make the MediaWriter infringe.

This aspect of Rowberg's report self-destructed when he admitted in deposition that "the database" in limitation 4, contrary to his report, could only refer back to the DICOM PACS medical image database in limitation 2:

> Q. So the question is, the Claim 9, the second limitation starts off: A database... And the fourth limitation states: A search module configured to search the database.
>
> My question is, is it your understanding that the database identified in the second limitation can be different than the database identified in the fourth limitation?
>
> A. (Reviews document.) Because it has defined "database" and then says "the database," I think it's referring back to the same one. So I would think it would be the same. (Rowberg Dep. 40:1-15)

This admission precludes Rowberg's "two database" theory of claim 9. As it is abundantly clear that searching two databases – one for images and the other for text reports is not substantially the same function, way or result as searching one database for selected and "related" images. Also, it is another proof that the text reports, because they cannot be stored in the same medical image database called for in limitation 2, cannot constitute "related medical image data."

5. The fifth limitation

Aside from its importance in rebutting Rowberg's construction of the fourth limitation, the fifth limitation is clear enough. It states that the CD burner loads a viewing program onto the CD along with the selected and "related images", both in DICOM-format. The MediaWriter does not do that.

B. The MediaWriter Does Not Infringe Claim 9

DatCard bears the burden of establishing that the Accused Product satisfy each claim limitation either literally or under the Doctrine of Equivalents. For the reasons discussed below it cannot raise a genuine issue of disputed fact from which a reasonable jury could conclude infringement.

1. The MediaWriter does not search for "related medical image data" as Rowberg construes it: All image data it retrieves is selected medical image data.

The menu of the MediaWriter appearing on the doctor's workstation gives a series of options for selecting the images the user desires. If a user wants to view all studies ever taken of the patient, he inputs the patient's name and a list of all studies belonging to that patient will appear. He can then check all studies or some of the studies. If he wants the most recent study, he can select that study by date or limit the search to begin with by date. Either way he will only get the study he is seeking. Or he can pick and choose whatever he wants from a list in the menu on the screen. In all these cases, the only images retrieved and received are those selected at the user's volition.[7]

If the user wants additional images he selects additional images as to that patient off the menu. Or he can move on to another patient. Either way, the search yields "selected" image data because it is the product of the user's selection. There certainly is no meaningful distinction, as far as the MediaWriter is concerned, between a selection of

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[7] This applies to Structured Reports, which were not available until well after the time period of the invention, and scanned-in images. Both these items are only burned on the disc if the user selects them. See Figure 1 above which includes an option to select SR – Structured Reports.

more data about the same patient and a selection of data for a different patient. It is all "selected."

There also is no meaningful distinction between selected and related image data as separate components of what is burned onto the CD's as called for in limitation 5. Once the user has viewed the available image studies, he separately selects which image studies he wants to have burned, all, some or none.

2. Reports Are "Selected" and do not Constitute "Medical Image Data"

Text reports are not DICOM images and therefore cannot satisfy the limitations for searching for related DICOM images and burning them onto a disc. Additionally, the text reports will not be burned on the disk unless the user makes a decision to include them. (See Figure 2 above.) There is an option which allows the MediaWriter to be preset to copy text reports from the workstation related to a patient's medical image. Even then, however, the user is presented with an option of deselecting reports or including them, which again constitutes a user's selection.

3. The MediaWriter does not search for text reports in the image database

By admitting that "database" in limitation 4 could only be the medical image database specified in limitation 2, and "related medical image data" could only be medical images, Rowberg demolished that part of his infringement analysis that depended on text reports stored in a separate folder on the hard drive meeting limitation 4's requirement of a search module "configured to search *the* database for related medical image data." The text reports stored on the hard drive (a) are not medical images and (b) are not stored in the medical image database specified in limitation 2, which only stores images.

To be sure, the MediaWriter can be configured to have text data to be burned onto the same CD that contains image data, but text data gets to the disk by a separate path and source from those employed to retrieve DICOM medical images as contemplated by Claim 9. See Ex. 258, Cavanaugh Dec. ¶¶2-17.

4. Infringement by equivalence is also precluded

Rowberg argues that if there is no literal infringement, then the text reports fed to the MediaWriter workstation hard drive via HL 7, Mitra Broker or other method satisfy limitation 4 under the Doctrine of Equivalents:

> "Pacsgear may also contend that using the Accused Products with a report broker that is not part of a PACS does not satisfy this claim element because the Accused Products would not search the same database for both selected medical image data and related medical image data.…*Even assuming that Pacsgear is somehow correct, it is my opinion that there are insubstantial differences between searching the same database for related medical image data and searching another database for related medical image data.* [emphasis added]." (Rowberg I, pp. 22-23, Ex. C).

Under the Doctrine of Equivalents, if an accused device does not literally meet a limitation in a patent, but has a feature which performs the same function, in the same way, with the same result, it may be found to infringe by equivalence. *Perkin-Elmer Corp. v. Computervision Corp.,* 732 F.2d 888 (Fed. Cir. 1984). A DOE analysis is confined to the particular limitation: it is not open to argue that the overall result of the entire claim is similar to the alleged equivalent result of the Accused Product. *E-Pass Technologies, Inc. v. 3Com Corp*, 473 F.3d 1213, 1221 (Fed. Cir. 2007), citing *Hilton Davis Chem Co., v. Warner-Jenkinson Co.*, 520 U.S. 17 (1997). As Dr. Horii concludes a device that searches a single database does not perform substantially the same function in substantially the same way to achieve substantially the same result as a device that searches multiple databases. (Ex. A, Horii Report, p. 15).

There is absolutely nothing in the claims, specification, figures, or file history giving the remotest hint that text reports are intended to be included along with images as related medical data. This alone would exclude that meaning because the patent specification does not enable the person of ordinary skill to practice the patent, or avoid infringing it. It would be invalid for non-enablement if the term were stretched to cover text reports. *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1384 (Fed. Cir. 2001)(Patent terms amenable to more than one construction should, when it is reasonably possible to do so, be construed to preserve their validity).

C. Independent Claim 15 Is Not Infringed Under Rowberg's Construction

Independent claim 15 is the same as claim 9 except presented in a method claim format, with the sole difference that it adopts an "optical disk" as the "single, portable data storage medium." Since a CD is an optical disk, our analysis of claim 15 is identical to the analysis of claim 9, namely that the claim is not infringed literally or by equivalence.

D. Independent Method Claim 16 Is Also Not Infringed

Claim 16 claims the method used in generating the CD with the "selected" and "related" data. Although the limitations are slightly rearranged, it consistently calls for "related medical image data." For that reason alone, it excludes "text reports". Additionally, it is "[a] method for selecting and automatically recording medical image data onto a data storage medium" and it requires that "the received *medical image data* be formatted in a standard medical imaging format" without distinguishing "selected" from "related" data (limitation 1) further confirming that the claim excludes text reports.

Claim 16 also requires that the production station (i) print a label and (ii) affix the label to the data storage device (i.e., CD). The MediaWriter, on the other hand, uses a CD Burner with an ink jet system that quickly and directly places information on the CD. It does not (i) print a label and then (ii) affix it to the CD. For this reason alone, the MediaWriter does not infringe Claim 16. Rowberg, after reviewing the MediaWriters CD Burner, contends that "The inkjet head is activated as the printing part and the ink is spread on the disc is the applied part." (Ex. J, Rowberg Dep. 185:13-20). Activating an inkjet head does not constitute "printing a label." The MediaWriter does not perform substantially the same function in substantially the same way to achieve substantially the same result as a device that requires a two-step process – print the label and affix the label – as required by the limitation.

E. Independent Method Claim 21 Is Also Not Infringed

Claim 21 is the same as Claim 16 with the exception that it specifically identifies the data storage medium as an optical disk. The MediaWriter does not infringe Claim 21 for the same reasons it does not infringe Claim 16.

IV. THE MEDIA WRITER CANNOT INFRINGE THE '597 TWO DATABASE PATENT

A. The '597 Patent

1. Construction issues

a. "additional medical data" is the same as "additional related medical data", and both are the same as related medical image data.

Method Claim 1 of the '597 patent, issued in 2010, is a refinement on Claim 9 of the '164 patent in that it requires "automatically" searching two different databases, the first database through one interface for "medical imaging data" pursuant to a "received request" (i.e. a selection) and the second through a different interface for "additional related medical data." Appendix C. It is DatCard's burden to establish that each of these limitations is satisfied.

The changes in wording to "request" instead of "selection" and "additional related medical data" instead of "related medical image data" are inconsequential. Rowberg testified that such claim terms were ambiguous, therefore necessitating reliance on the specification. (Rowberg Dep. 65:3-25)

DatCard's proposed construction that the additional related medical data can be text data must be rejected for these reasons:

The specification consistently uses "related data" to refer to image data. All ten uses of "related data" in the specification (App. A, col. 8:25-60) in context can only refer to image data. See, in particular, the references to "PACS systems stored in the 'related data storage' field" which the applications server searches for "related data." Col. 8:44-46. The only data identified as being stored on these PACS systems is image data and the only data sent to the production station from these PACS systems is "the medical image data originally received in step 132 and the related medical image data." (App. A, '164 Patent- Col. 6:38-58)

The specification and figures nowhere mention or illustrate the storage, retrieval, or copying of text data.

The claim would be invalid if interpreted to include text data, because the patent does not enable the person of ordinary skill to practice it. See e.g., *Nat'l Recovery Tech., Inc. v. Magnetic Sep. Syst. Inc.*, 166 F.3d 1190 (Fed. Cir. 1999)(Motion for summary judgment for invalidity upheld where patent's specification does not enable person of ordinary skill in the art to practice claim without undue experimentation; in this case, the complete omission of language encompassing text data from the specification and figures provides no starting point from which a PHOSITA can base his experimentation towards successfully practicing the invention).

In the file history, there is no suggestion that "related data," "related medical image data," "additional related medical data" or any other variations encompasses text data.

The continuation application leading to the '597 was filed on June 24, 2009, two years after MediaWriter was introduced on the market. DatCard had the luxury of designing its claims in an attempt to entrap the MediaWriter, but never gave any hint to the Patent Office that text data was included, not just in pursuing the '597 application but in *ten years* of prosecuting these patents.

Dr. Rowberg, in any event, admitted that the "related data" was limited to medical image data. (Ex. J, Rowberg Dep., pp. 119-121). He also conceded that medical data is synonomous with medical image data and would not include text reports. (Ex. J, Rowberg Dep., p. 69:3-7)

b. "automatically"

The other disputed term in the '597 is "automatically." It appears in 6 of the seven limitations: "automatically searching a first computer database" (lim. 2), "automatically retrieving the first set of medical imaging data…," (lim. 3), automatically searching , based on the received request, a second computer database…" automatically searching, based on the received request, a second computer database ….for additional medical..." (lim. 4)

automatically receiving the additional related medical data (lim 5) and "automatically generating a portable computer readable medium…(lim. 6).

This feature is discussed in the specification in the context of pre-setting the system to automatically search for related medical image data, and is illustrated in the Figure 5 flow chart. The patent specification uses "automatically" variously meaning "without prompting for user selection" (7:53-55) and "without asking for user direction" (8:48-49).

2. Non-infringement of claim 1

a. No automatic search

The MediaWriter does not infringe because there is no mechanism for automatically broadening the user's selection to encompass image data outside the scope of the selection. The user simply selects what medical images are desired, gets them and no others. There is no automatic search; the user must make another selection to obtain additional materials.

Additionally, the MediaWriter does not satisfy all the limitations because the operations set forth in the claim do not occur automatically. That is the claim requires that upon "receiving, via computer-implemented interface a request for medical data related to the patient" all the other steps occur "automatically" resulting in a CD containing selected medical image data, additional related medical data and viewing software.

The MediaWriter does not work that way. To the contrary, after receiving a request of medical data related to the patient, a user of the MediaWriter must still select the image studies by positioning the cursor over a box next to each study and clicking the computer's mouse, positioning the cursor over and clicking on the Burn Studies button, at which point a Confirm Burn dialog box will appear. Next the user can select whether or not it wants to include reports and only after it approves of the selections on the Confirm Burn dialog box and clicks on the "Confirm" button, will the images be burned on the CD. (Ex. 217, MediaWriter User's Manual 4.0. p. 10-13). This multistep process is outside the scope of the claim limitations and their equivalents.

b. The MediaWriter does not automatically search two image databases

Rowberg identifies HL7 databases, Mitra Report Brokers and a second PACS or other modalities as the "second database" which the MediaWriter searches for additional medical data. (Ex. C, Rowberg I, p. 44-45). Rowberg next contends that the Claim's 5th limitation (*automatically receiving the additional related medical data)* is satisfied by the Configure Reports option added to the MediaWriter in version 3.0. (Rowberg I, Ex. C, p. 46). As discussed above, the MediaWriter can not search for or receive images from any database through the Configure Reports option. (Ex. 258, Cavanaugh Dec., ¶¶ 2-17). Morever, DatCard has failed to provide any evidence demonstrating that anyone has used the MediaWriter to conduct, via the Configure Reports option, a search of a second PACS or modality for medical images, nor can they! *Standard Havens Products, Inc. v. Gencor Industries, Inc.,* 953 F.2d 1360, 1374 (Fed. Cir. 1991), *cert. denied,* 506 U.S. 817, 121 L.Ed.2d 28, 113 S.Ct. 60 (1992)(The method claims of the patent at issue were held not directly infringed by the mere sale of an apparatus capable of performing the claimed process, as method claims are directly infringed only when the claimed process is *performed*.) In short, the only images received are those initially selected by the user. Additionally, as discussed above, even text reports are not automatically included on the CD as they are only included following a volitional act of the user.

3. Construction and non-infringement of claim 6

Claim 6, a system claim, rearranges the sequence of the limitations of claim 1, and adds the additional limitation that the data in all instances is "related to the patient." It also deletes the term "automatically" from each limitation although it is included in the claim's preamble. The Claim requires a first and second database which store medical images (lims. 1 & 2) an application server which is connected to both databases (lim. 4), which after receiving a request, is configured to send a search request, "based on the received request" (lim. 3) to a first database for medical imaging data, and to a "different" "second database" distinct from the first database for additional medical data related to the patient.

(lims. 5 and 7). The system receives the "additional related medical data" (lim 8) and the productions station burns "the first set of medical imaging data"…and the "additional related medical data" onto the CD.

The data, regardless of the formulation, is all DICOM image data, for the reasons discussed above and as Rowberg admitted.

The limitation that the second search is based on the first request means that there is no second selection of data by the user: it is triggered <u>automatically</u> by the original request "without user intervention."

As with Claim 1 of the '597 Patent, the MediaWriter does not infringe claim 6 because in order to do so it must get image data from two different databases. The fourth limitation specifically requires an application server connected to two databases capable of providing the images, which are ultimately burned on to the CD. Rowberg contends this element is satisfied by the MediaWriter's connection to (i) a PACS and (ii) any of the following: a second PACS, a modality, HL7 reports database or a Mitra Broker in connection with the Configured Reports option. (Ex. J, Rowberg Dep., pp. 51-53). As discussed above, however, DatCard has not provided any evidence that the application server has ever been coupled to a second PACS or modality in connection with such a search. Additionally, the Configured Reports option does not allow one to search for or retrieve images - it only allows for the retrieval of text reports.

As discussed above, the claim language requires that the search of the second database occur automatically "based on the (original) received request" (Appendix C., lim. 7). The MediaWriter does not automatically burn reports or any images on to CDs. Instead, after the user inputs the patient's name, the user must select the studies by positioning a cursor over a box next to each desired image study and clicking a mouse button, positioning the cursor over and clicking on the Burn button (Figure 1 above), and then making a decision in the Confirm Burn dialog box (Figure 2 above) whether or not to include the reports AND then clicking on the Confirm button. If all those user steps are

not completed the images from the PACS archive and any text reports resulting from the Configured Reports option, will not be placed on the CD.

B. No Infringement By Equivalence

There can be no infringement by equivalence of the '597 patent, because the MediaWriter does not accomplish the same function in the same way to achieve the same result: There is no automatic search for unselected image data nor is image data obtained from two databases.

IV. THE MEDIA WRITER CANNOT INFRINGE THE '174 PATENT

A. Claim Construction of the '174 Patent

The '174 patent[8] parallels the '164 patent, except that it is slightly more broad in that it allows for images to originate from a single modality instead of the plurality required by the '164 Patent. Claims 1 and 8, the two independent claims, use similar terms and for purposes here can be analyzed together. The claims use the term "related data" instead of "related medical data" or "related medical image data." As discussed above, however, for purposes of the patent claims "related data" necessarily means related medical image data in DICOM format.[9] (See above discussion of "medical data" and "related data" in connection with the '597 Patent). Additionally, the fourth limitations of the claims mandates that the search module automatically search the database for related data based on the user selection. The term "automatically" would have the same meaning used above – i.e., no user intervention.

B. The MediaWriter Does Not Infringe Claims 1 And 8 Of The '174 Patent

As with the '164 Patent, both the selected and related images must come from the same database. The second limitation requires the database be configured to store medical images and the fourth limitation requires that the same database be searched automatically

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[8] See Appendix D.
[9] In fact, Claim 5 of the '174 Patent confirms this interpretation as it states: "selected medical image data and *related medical image data"* were recorded onto the data storage medium. Showing at the the applicant considered the terms to be synonymous.

for related images. The two databases identified by Dr. Rowberg to satisfy the second limitation are (i) the local hard drive which stores the medical images but is not searchable by the user and (ii) PACS/imaging modalities. (Ex. C, Rowberg I, p. 55-56). Dr. Rowberg then identifies the following different "databases" which he contends satisfies the fourth limitation of Claim 1. (Ex., C, Rowberg I, p. 58-61):

1) *The MediaWriter is capable of storing reports received from HL7 feeds or brokers on its hard drive.* The files which store these text reports on the MediaWriter's local drive are not the same "database" Rowberg identified in connection with second limitation. Additionally, the reports themselves are text reports and not image data.

2) Dr. Rowberg next contends that the "related data" includes DICOM Structured Reports or DICOM images, which are scanned into a PACS. As discussed above, these Structured Reports and/or scanned images are directly associated with images on the PACS and would be burned on to the CD only if they were "selected" by the user. See Figure 1 above.

3) Dr. Rowberg also contends the MediaWriter is configured to search the database for related data "via a report broker, such as a Mitra broker". Again, the reports generated by these brokers are text reports and not images. Additionally, the Mitra brokers and other brokers are a separate and distinct database compared to the "database" Dr. Rowberg identified in connection with the second limitation of Claim 1.[10]

All his proposed "database" options fail to satisfy the claim language.

The fourth limitation also requires that the search for related data occur automatically. As discussed above in connection with the '597 Patent, the user must

[10] Dr. Rowberg opines that there are "insubstantial differences between searching the same database for related medical images data and searching another database for related medical image data." (Ex. C, Rowberg I, pp. 60-61) While technically-speaking, searching multiple databases versus a single database could be accomplished by one skilled in the art, the scope of Claim 1 is specifically limited to searching a single database.

intervene on multiple occasions before the search for related data occurs – even if "related data" includes reports (e.g., position cursor and clicking the mouse to select studies, position cursor and clicking the Burn button, select whether or not reports should be included, click the Confirm button, etc…).

In light of the above, the MediaWriter does not infringe Claims 1 or 8 of the '174 Patent.

C. No Infringement By Equivalence

There can be no infringement by equivalence of the '174 patent, because the MediaWriter does not accomplish the same function in the same way to achieve the same result: a system which searches multiple databases versus a single database, searches for text reports instead of images and requires user intervention as opposed to occurring "automatically" - performs a substantially different function in a substantially different way to achieve a substantially different result.

CONCLUSION

For all the above reasons, the MediaWriter does not infringe the three Search/Burn Patents.

Respectfully submitted,

Dated: January 16, 2012

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DATCAR.003A1

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number:	09/761,795	Confirmation Number: 5945
Applicant:	Wright et al.	
Filing Date:	17 January 2001	
Art Unit:	2621	
Examiner:	Huy Thanh Nguyen	
Customer Number:	20,995	

Commissioner for Patents
Post Office Box 1450
Alexandria, Virginia 22313-1450

DECLARATION OF KEN WRIGHT UNDER 37 C.F.R. § 1.132

Sir:

I, Ken Wright, declare as follows:

1. I have been involved in Medical Informatics for the last twenty years within large hospital environments in which my primary role was in evaluating medical applications that applied to Radiology. In addition, I have actively participated in a number of societies over the last twenty years relating to Medical Informatics such as HIMMS (Health Information Management Systems), SCAR (Society of Computer Applications in Radiology) and as a practicing Radiologic Technologist (ARRT, CRT). I consider myself skilled in the art of development and implementation of healthcare information management systems that operate in compliance with the Digital Imaging and Communications in Medicine ("DICOM") standard.

EXHIBIT 44
5
5/4/11 - 5 B

DAT000543

Exhibit 5

Application Number 09/761,795

2. I am a co-inventor of the invention claimed in U.S. Patent Application 09/761,795, which was filed on 17 January 2001, and which is referred to herein as "the '795 Application".

3. The '795 Application discloses, among other things, systems that can be used to select and automatically record medical image data onto a data storage medium. Such systems typically include an application server that receives medical image data from a medical image database. The medical image data is formatted in a standard medical imaging format used by specialized computers for viewing medical images. The application server allows users to select medical images of interest and search for additional medical images that are related to the selected images. The selected and related medical images can then be recorded onto a portable data storage medium, such as a compact disc, using the standard medical imaging format. A viewing program is also recorded onto the storage medium with the medical images. The viewing program allows the medical images stored on the storage medium to be viewed on widely accessible computers that are not specifically configured with standard medical imaging software.

4. The inventions disclosed in the '795 Application provide a substantial improvement over the conventional methods for accessing and distributing medical image data at the time the invention disclosed in the '795 Application was made. As far as I am aware, before the invention disclosed in the '795 Application was made, existing systems required the use of viewing workstations that were specifically configured to view medical image data stored in a standardized medical imaging format, such as the DICOM format. This substantially limited the distribution and portability of medical image data.

5. I am familiar with the course of prosecution of the '795 Application, including the Office Action mailed on 20 April 2007, in which the Examiner cited U.S. Patent

6,241,668 ("Herzog") in view of U.S. Patent 5,909,551 ("Tahara"), U.S. Patent 5,272,625 ("Nishihara"), U.S. Patent 6,260,021 ("Wong"), and U.S. Patent 6,954,802 ("Sutherland"). I have carefully reviewed these references.

6. Herzog discloses a system for capturing, processing and storing medical image data (1:5–10). The Herzog system includes several devices, referred to as digital imaging modalities, that are configured to acquire medical images; examples of such modalities include a computed tomography unit, a magnetic resonance unit, a digital subtraction unit, and an x-ray unit (2:21–26). The Herzog system also includes a diagnostic station that is configured to acquire medical image data from a number of different sources, such as from the digital imaging modalities (3:23–28), from a digital image archive (3:28–31), or from a scanner used to scan relevant documents (3:32–36). The medical image data acquired by the diagnostic station can be recorded onto a compact disc using a compact disc writer (3:43–49).

7. Other than a statement that certain imaging sources "offer standardized JPEG software interfaces" such that the "images thusly acquired can be made available over the Internet" (4:15–23), Herzog ignores the question of which format should be used to store the medical image data on the compact disc. Furthermore, even assuming that a standardized medical imaging format is to be used, Herzog also ignores the question of how this data could be accessed and viewed on widely accessible computers that are not specifically configured with standard medical imaging software.

8. Sutherland discloses formatting standard medical images such that they can be widely accessed by computer. For example, Sutherland discloses use of PC-based review stations that are "configured with specialized image viewing software that can read specific file formats" (4:9–13). Sutherland further discloses recording a patient study on a medium "that can be viewed by any DICOM-compliant viewing station ... which supports the appropriate modality

objects" (7:13–16). Thus, Sutherland contemplates the need for a DICOM-compliant viewing station, and therefore an ordinarily skilled artisan would not understand Sutherland as suggesting the use of a viewing program that allows for viewing of medical image data on widely accessible computers not specifically configured with standard medical imaging software for viewing of medical images.

9. Tahara discloses an interactive multimedia information recording system (1:8–11). An ordinarily skilled artisan would not look to the teachings of Tahara when seeking to improve upon the shortcomings of conventional systems that require the use of viewing workstations that were specifically configured to view medical image data stored in a standardized medical imaging format, such as the DICOM format. In particular, an ordinarily skilled artisan would not recognize that the multimedia system disclosed in Tahara would be applicable to systems used to manage healthcare information. An ordinarily skilled artisan would not recognize that the Tahara system would be applicable to a system, such as the Sutherland system, that is used to manage medical imaging information in a way that allows medical images stored on a portable recording medium using a standard medical imaging format to be viewed on widely accessible computers that are not specifically configured with standard medical imaging software.

10. Nishihara discloses a medical image data management system for use with a distributed image database and a medical image data filing system (1:6–10). This system allows imaging modalities to extract image filing destination information from a filing destination file and transfer generated images to a filing apparatus that indicated by the extracted filing destination information (10:20–37). An ordinarily skilled artisan would not understand this arrangement to be applicable to the invention disclosed in the '795 Application. Specifically, the system disclosed in Nishihara does not address the shortcomings of medical image data management systems, such as that disclosed in Sutherland, that require the use of viewing workstations that are specifically configured to view

medical image data stored in a standardized medical imaging format, such as the DICOM format.

11. Wong discloses a computer system used to provide distribution of and access to medical image data (1:7–12). The system optionally includes a security object server that logs an audit trail of user sessions that access the medical image data (10:43–47). An ordinarily skilled artisan would not look to the teachings of Wong when seeking to improve upon the shortcomings of conventional systems, such as the system disclosed in Sutherland, that require the use of viewing workstations that are specifically configured to view medical image data stored in a standardized medical imaging format, such as the DICOM format. In particular, an ordinarily skilled artisan would not recognize that the audit system disclosed in Wong would help address the shortcomings of the Sutherland system, especially since the shortcomings of the Sutherland system are not related to the features disclosed in Wong.

12. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued therefrom.

Dated: 7-19-07 By: Ken Wright

Ken Wright

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DEPOSITION EXHIBIT 77

PENGAD 800-631-6989

Evolution of the Filmless Cardiac Angiography Suite: Promise and Perils of the Evolving Digital Era

Steven E. Nissen, MD

Although cineangiography has been in use for 35 years, it has important limitations. Films are expensive to produce, cannot be readily copied or transmitted electronically, are bulky, and require a large storage space. Digital angiography will soon replace film for archiving cardiac catheterization images, ultimately offering powerful new capabilities at a reduced cost. The transition toward the filmless angiogram is characterized by both great promise and important risks. Current nonfilm archiving systems (such as super-VHS videotape or analog optical disks) have not met the needs of the cardiovascular community, owing to poor image quality and resolution inferior to that of cine films. Analog storage media can result in a standard error in lesion measurements exceeding 1 mm and have a suboptimal signal-to-noise ratio. While digital media record adequate image detail, proprietary formats preclude the universal compatibility supplied by cine film. As a consequence of incompatibility, referred patients must undergo repeat catheterization prior to surgery or intervention. To resolve the compatibility problem, a committee established by the American College of Cardiology in conjunction with manufacturers (DICOM) has developed a standardized digital recording format using CD-ROM to transfer images between medical centers. The availability of this standardized interchange medium will have a positive impact on research as well as on patient care by eliminating barriers to image exchange throughout the cardiovascular community. Support for the DICOM approach by practitioners is vital to the transition to digital future.

(Am J Cardiol 1996;78(suppl 3A):41–44)

For >35 years, cine film has served as the predominant recording medium for coronary angiography. During this era, angiographic film has served the cardiovascular community well, providing a stable and standardized method for a broad range of clinical and research applications. These included local review, long-term storage, and long-distance transportation of images for patient care or research studies. Now, in the evolving era of computerized medicine, cine film is facing extinction as the principal modality used to record coronary angiography. What recording approach will replace cine film? How will we manage the transition to a digital environment? These are critical questions facing the cardiovascular profession that will affect nearly every practitioner.

The technologic evolution toward a filmless angiography suite began in the early 1980s, when angiographers discovered the power of digital recording to provide virtually immediate high-quality images for diagnostic review.[1] Within a few years digital angiography replaced videotape as the primary recording modality for in-room viewing during diagnostic and interventional angiography. Naturally, cardiovascular practitioners soon began to evaluate whether digitally recorded angiograms could also serve as an archive medium for long-term storage of angiography. Cardiologists also considered the possibility that digital angiograms could replace the interchange function of cine film, allowing long-distance communication via physical media or via electronic networks. This transition toward the filmless angiogram offers great promise but also presents important risks, which virtually everyone who practices invasive cardiology must understand to guide their laboratory into the digital realm.

LIMITATIONS OF CINEANGIOGRAPHY

Although cineangiography currently serves as the dominant means of recording angiographic data, it has important limitations. Since each film is a unique record, it is impossible for the laboratory, performing physician, and surgeon each to have their own copy. For angiographers who participate in clinical trials or when patients move to a new location, it has been necessary to ship films across country at great expense. Similarly, if a patient or physician requests a second opinion or when patients are referred for tertiary care, the unique film record must accompany them. There is currently no easy way to transmit film angiograms electronically for remote consultations.

In addition, because of its silver content, the film itself is rather expensive. The estimated cost for recording a single patient study on film averages approximately $100. A laboratory that performs 2,500 angiograms a year will spend a quarter of a million dollars on film alone. Limited replay or review stations for film are very costly—starting at about $25,000—with the most advanced film projectors exceeding $50,000. The 35-mm film reels are bulky and require a substantial amount of storage space. Since the images cannot be duplicated, a careful internal tracking system is needed to retrieve them. Nearly every invasive practitioner has experienced the frustration of seeing a patient with chest pain in

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PII S0002-9149(96)00492-4

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Exhibit 77

the emergency room a few weeks following an intervention and being unable to obtain the films because they are on someone's desk or lost in the film library.

THE DIGITAL ERA OF ANGIOGRAPHY

As the digital era of angiography evolves, we will begin to see enormous benefits in patient care as data become more widely and rapidly accessible. We can anticipate—and it is already a reality in a few laboratories—a high-speed network for relaying images and related patient data. When a patient arrives in the emergency room, the clinician can go to a terminal and call up that patient's previous angiograms to determine whether it is best to administer a thrombolytic, send the patient to the catheterization lab, or perhaps do nothing. Because of the inherent ability of digital data to be readily copied, multiple parties can have identical copies of an angiogram, while the original is kept in the archives or film library.

In economic terms, the cost of digital storage is already less than $10 per patient and will predictably decrease further within a few years. Even at today's prices, this represents about a 90% reduction in the cost of recording angiography. In addition, with the development of digital archiving technologies, expensive mechanical film projectors will not be required. At the Cleveland Clinic, we have approximately 50 such projectors—an investment of substantial proportions. Ultimately, it seems probable that the physician's multifunction personal computer will serve as an angiographic review station. The PC-based angiographic "projector" can be used to make slides, videos, or other materials for presentation from clinical images. Because the storage of digital images can be much more compact, there will be no need for the large film libraries we now maintain.

DRAWBACKS OF NONFILM ARCHIVING SYSTEMS

In Europe, the United States, and Asia we have seen the gradual transition to nonfilm archiving systems proceeding at different rates. In the United States about 15% of labs are currently filmless, while in Europe the conversion rate is much higher, in some countries (the United Kingdom) exceeding 50%. Unfortunately, this precipitous transition to filmless catheterization has turned out to be a catastrophe for cardiovascular medicine. Since no standard for recording and interchange has existed, most current filmless laboratories are completely isolated. They can neither provide nor receive angiograms from other sites for clinical care or research. In addition, the existing archival systems meet the needs for accurate recording of angiograms to a variable extent. These systems include super-VHS videotape, analog optical disks, D2 digital videotape, 8-mm Exabyte tape, and a variety of proprietary products. None of these products has been able to meet all the needs of the cardiovascular community.

Super-VHS videotape, for example, has been widely promoted, but is an extremely poor and unacceptable substitute for cine film. Under the best circumstances, super-VHS resolution is about half that of a cineangiogram—i.e., about 275 lines of resolution for a 512 × 512 pixel image. If you consider that angiography itself offers minimally adequate resolution for diagnostic purposes under optimal conditions, anything less will result in a large number of misdiagnoses. Recent data show that super-VHS videotape exhibits a standard error in lesion measurements approaching 1 mm for larger patients (high KvP levels). Accordingly, at ±2 standard deviations, the 95% confidence interval approaches 2 mm—nearly as large as the coronary vessel itself in many cases. Clearly, super-VHS videotape is not suitable for surgical or interventional decision making. Accordingly, most referral centers that receive such videotapes find it necessary to recatheterize routinely prior to surgery—a disservice to the patient who must undergo a second procedure and unnecessary additional cost and risk.

Somewhat better than super-VHS videotape and very popular in some countries (particularly France) are *analog optical disks*, which typically consist of 12-inch platters. These analog storage devices exhibit marginal image quality. According to recent data, analog optical disks (like S-VHS tape) also exhibit surprisingly large standard errors in lesion measurements, most evident when other factors, such as large patient size or compound angles, impair underlying image quality. In addition, the signal-to-noise ratio (SNR) at the source (video camera) exceeds 63 decibels, whereas analog optical disks are limited to about 46–48 decibels and super-VHS videotape to only 43 decibels. For every 3 decibels, the noise level is doubled. Finally, with no mass market outside of medicine, analog disk media are expensive and will soon become obsolete. Ultimately, hospitals that choose such systems will either have to convert their angiographic image files to a new format or leave them behind.

The Tower of Babel: Apart from the aforementioned limitations in image quality, a more fundamental problem confronts the transition to a filmless angiogram. Until recently, virtually all filmless angiographic systems were proprietary. Thus, images recorded using one manufacturer's system could not be reviewed on equipment produced by another vendor. This lack of standards was best summarized in a position statement of the American College of Cardiology (ACC) that warned of the coming "Tower of Babel" in the catheterization laboratory[2]:

> Existing filmless digital archiving systems for storage of cardiac catheterization studies all lack the one critical feature supplied by 35-mm film—worldwide standardization. Accordingly, installation of such a system deprives the patient and physician of the opportunity for exchange of angiographic images between medical centers for clinical care research.

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Incompatibility of formats for image transfer not only represents a major impediment to good patient care, it also has serious negative implications for research. Since virtually all major multicenter trials of coronary interventions or thrombolysis therapy require core laboratory analysis of cine films, hospitals with filmless catheterization suites can expect to be systematically excluded from such trials. Ultimately, widespread conversion to nonstandard archiving systems will limit the number of possible participating centers and thus compromise clinical research.

The Digital Imaging and Communication for Medicine Effort: Four years ago, in an attempt to avert this calamity, several experts in digital imaging, including myself, urged the ACC (through the Cardiac Catheterization Committee, chaired by Carl Pepine) to take a proactive role in developing a digital standard. The goals of this effort included maintaining the quality of angiography during the transition to digital imaging and supporting exchangeability of images for clinical care and research. As a result, a committee was formed that consists of physician-representatives appointed by the ACC and members of the National Electronics Manufacturers Association (NEMA), which includes all the major x-ray vendors and angiographic media manufacturers. This standardization group was organized within the framework of an existing effort known as the Digital Imaging and Communication for Medicine (DICOM), which is seeking to complete a broad range of standards with medical imaging.

The DICOM angiographic committee, chaired jointly by me and an industry representative, has made significant progress toward developing an effective interchange standard for cardiovascular imaging. To ensure that this will be a worldwide standard, we have invited and received considerable support from our European colleagues through the European Society of Cardiology. The American College of Radiology has also been very supportive, and representatives participate in the monthly meetings held in Washington, DC. Of equal importance, the cardiovascular standardization effort has expanded to nonangiographic modalities, including echocardiography and nuclear cardiac imaging.

MEDIUM FOR DATA INTERCHANGE

Currently, we are completing a standard for interchange that will greatly increase the convenience of angiographic imaging by providing a simple means of conveying angiograms from site to site (Figure 1). At the 1995 ACC meeting, the x-ray angiographic and echocardiographic DICOM committees demonstrated this standard for the first time. Over 5,000 CD-ROM demonstration disks were handed out. The format of the disks was based on a variant of the CD-ROM now commonly available around the world at a very low cost. Because the disk was for demonstration only, images were pre-selected, and 28 x-ray vendors demonstrated the ability to read and display them on their proprietary systems or workstations.

FIGURE 1. The DICOM interchange medium (CD-ROM) is designed to serve as a means of transferring digital angiograms from site to site. The DICOM standard does not specify the method for archiving angiograms within a hospital or catheterization laboratory.

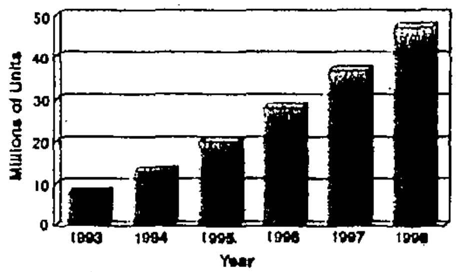

FIGURE 2. Projection of CD-ROM units installed by the year 1998.

At the 1996 ACC Scientific Sessions, the demonstration was even more elaborate, including read and write interoperability exhibited by about 20 vendors. The demonstration CD-ROM contained not only angiograms but also ultrasound images and several nuclear studies. We distributed a public domain DICOM "viewer"—a simple computer program that enabled the clinician to review these images in a PC environment using any X86 PC (e.g., 486, Pentium), along with educational materials. We also provided lectures and tutorials on DICOM at the ACC booth. This demonstration heralded the coming era in which the patient record can include all relevant angiograms, a thallium scan showing ischemia, and even ultrasound studies showing ventricular function. With DICOM, the clinician will be able to view all these studies from a common workstation.

Why did we choose CD-ROM as the preferred format? There were many reasons, but the main ones include the ubiquity and low cost of this medium. At present, the installed base of CD-ROM drives in the United States is >30 million units; by the year 1998, this number will approach 50 million (Figure 2). Since a fast CD-ROM drive costs a few hundred dollars, image access with this technology will be much more affordable than the expensive proprietary formats. The capacity of the CD-ROM (650 megaby-

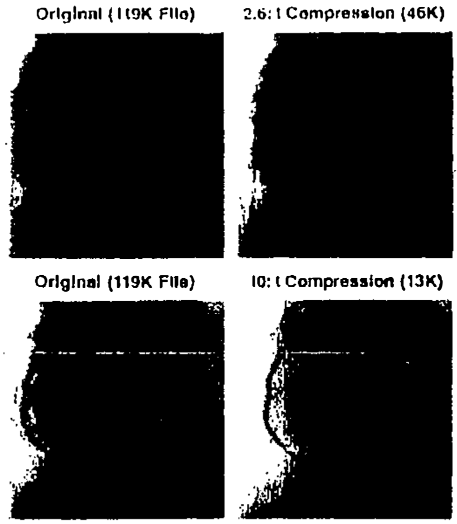

FIGURE 3. Comparison of "lossless" Image compression (A) and lossy compression (B) showing complete reversibility of the former and some destruction of the latter on decompression. Although the Huffman code compression scheme is lossless, it achieves data reduction of only about 2 : 1. The compression methods of the Joint Photographic Experts Group (JPEG) can be tuned to produce compression ratios over a wide range, typically from 4 : 1 to 50 : 1. The differences between the two approaches may be less apparent in the print reproduction of these images.

tes) is sufficient to store >99% of all angiograms on a single disk if images could be compressed at a 2 : 1 ratio.

IMAGE COMPRESSION AND REVERSIBILITY

Selecting a method for data compression represented an important task for the DICOM committee. To achieve the needed 2 : 1 ratio, we chose a method of compression termed "lossless" because it is completely reversible (Figure 3A)—i.e., when you decompress the file for review, the image will be identical to the uncompressed original image. However, despite 2 : 1 compression, the current data transfer rates of the CD-ROM are sufficient for replay of angiograms at only 7.5 frames per second—about one-fourth the typical frame rate used for reviewing film. To improve replay speed, two vendors of x-ray equipment have introduced a proprietary extension of the DICOM format that uses "lossy" compression. With this approach, a higher degree of compression is achieved (yielding faster playback from CD-ROM) but at a cost of being "destructive." Thus, when you decompress the image, you don't get back the exact same image that you originally compressed (Figure 3B).

It is important for clinicians to know, however, that lossy compression is *not yet* a part of the DICOM standard. Before concluding that the lossy compression technique is clinically acceptable, the DICOM committee (through the ACC) is sponsoring a multicenter study of this compression scheme. Clinicians all over the country will be asked to participate in this study by blindly viewing and comparing images that have either been compressed (lossy) or never been compressed. The responses will be evaluated statistically by comparison with colleagues' responses. When fully analyzed, these data will establish the clinical safety of lossy compression, at which time its addition to the standard will be considered.

RECOMMENDATIONS FOR CONVERSION

With the following background in mind, what should we recommend to laboratories involved in the transition to filmless angiography? For centers involved in clinical research, film or DICOM digital angiograms are absolutely necessary for interventional studies requiring quantitative coronary angiography. The errors inherent in media such as super-VHS videotape or analog optical disks are sufficiently large that study results are likely to be compromised. Therefore, centers that use videotape archiving should not be included in these clinical studies, since they will not yield optimal results.

In terms of clinical angiography, labs must avoid super-VHS videotape, proprietary digital tapes, analog optical disks, or any of the other nonstandard (non-DICOM) filmless "solutions." I strongly recommend that you keep your cine films until the standard is fully established. This will enable you to continue to communicate with the larger cardiovascular community.

Carefully evaluate new archiving systems, particularly media costs, speed of retrieval, and future growth capability. The DICOM committee has not specified how hospitals might store studies internally. Accordingly, there is no DICOM-recommended archiving system. Hospitals are free to choose from among many alternative systems. If you acquire new laboratories, the purchase contract should specify that the system will comply with the DICOM standard. As we move from film-based to filmless angiography, this will allow information to be readily exchanged with colleagues around the world for research and patient care.

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PG015927

Self contained off-line media for exchanging medical images using DICOM-compliant standard

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ABSTRACT

The goal of this project is to develop and implement off-line DICOM-compliant CD ROMs that contain the necessary software tools for displaying the images and related data on any personal computer.
We implemented a hybrid recording technique allowing CD-ROMs for Macintosh and Windows platforms to be fully DICOM compliant. A public domain image viewing program (OSIRIS) is recorded on the CD for display and manipulation of sequences of images. The content of the disk is summarized in a standard HTML file that can be displayed on any web-browser. This allows the images to be easily accessible on any desktop computer, while being also readable on high-end commercial DICOM workstations. The HTML index page contains a set of thumbnails and full-size JPEG images that are directly linked to the original high-resolution DICOM images through an activation of the OSIRIS program. Reports and associated text document are also converted to HTML format to be easily displayable directly within the web browser.
This portable solution provides a convenient and low cost alternative to hard copy images for exchange and transmission of images to referring physicians and external care providers without the need for any specialized software or hardware.

Keywords: Teleradiology, PACS, DICOM off-line media, CD ROM, telemedicine

1. INTRODUCTION

With the recent development of the DICOM standard, most manufacturers have adopted the DICOM format for image storage and communication on most imaging devices. In addition to the DICOM communication protocol, one of the attractive features of the standard is the definition of an "off-line" media format for image files (defined in Chapter 10 of the DICOM standard). This extension of the standard was initially mostly adopted in cardiology for off-line storage of angiography and echocardiography image sets. More recently, it was also adopted as a format for storage of images from other imaging modalities on off-line media such as CD ROMS or DVD disks. It is now becoming a very attractive alternative to film and hard copy prints for exchanging medical images and data between institutions as well as between the image providers and the rest of the medical community. The usage of DICOM off line media such as CD-ROMs suffers, however, from serious restriction due to the limited availability of viewing software. The need for storing images on off line media is increasing in clinical setting that will tend to operate filmless. To provide patients and referring physicians with the results of a radiological examination require that these data can be easily accessible without the need for specialized hardware or software.

We elected to develop and implement a technique for generating off-line DICOM compliant CD ROMs that will also contain the necessary software tools for displaying and manipulating the images on any personal computer. The goal of this project is to provide patients and referring physicians with electronic copy of their medical record that can be easily reviewed on any personal computer without specialized hardware or software while maintaining the integrity of the full resolution original images in a DICOM compliant format. We envision this alternative to be a replacement for hardcopy and film copies in a filmless environment.

2. MATERIAL AND METHODS

We implemented a hybrid recording technique allowing CD-ROMs to be readable on Macintosh and Windows platforms while remaining fully compliant with the DICOM standard. The system was developed to be easily operated as a stand-alone unit in a DICOM compliant network. The system allows to perform the following operations sequentially:

1. Retrieve and download image files
2. Sort and assemble images in corresponding studies and series

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3. Retrieve and match corresponding data documents (reports, letters etc.)
4. Create the hierarchical data structure and the corresponding directory file (DICOMDIR file)
5. Generate low-resolution thumbnails and JPEG images
6. Create the HTML pages with the content of the disk
7. Attach information and instruction pages
8. Add the DICOM viewing software (OSIRIS imaging software)
9. Create the CD ROM in a hybrid (Macintosh and Windows) format

Authoring software: The software was developed and implemented on a Macintosh platform and is driven through a simplified user interface allowing any user with limited training to easily create and edit CD ROMs on demand.

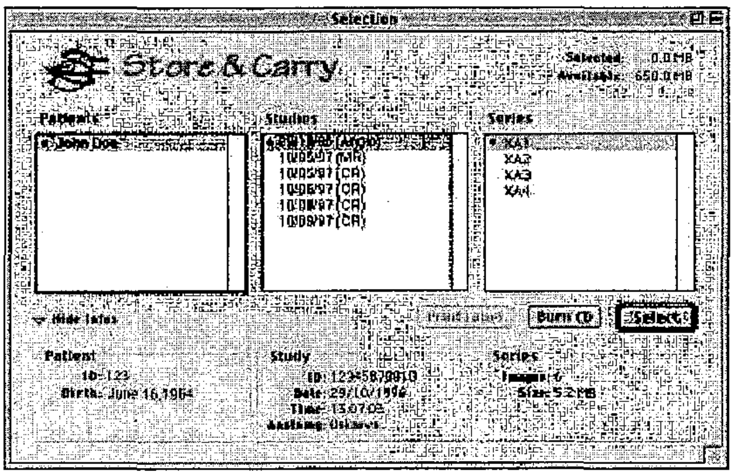

Figure 1: Main dialog window of the software allowing the selection of images and related data to be stored on the CD-ROM

The software also automatically creates the HTML pages that will display the content of the disc in any web-browser on any computer platform. In addition to the images in DICOM format a low resolution set of thumbnails and JPEG compressed images are created to be easily displayable in the browser for review and retrieval of the content of the disk. These images that are displayable in the web browser provide a hyperlink to the original images in DICOM format. To be displayed the DICOM images require a special viewing software that is also provided on the disk.

DICOM viewer: A public domain image viewing program called OSIRIS developed at the University of Geneva is also recorded on the CD for display and manipulation of sequences of images on either hardware platform. This software allows to display and analyze series of DICOM images at their full resolution. Images can be adjusted (window and level) in their full dynamic range independently from the display characteristics of the computer being used. The OSIRIS software also supports dynamic display of sequences of images as well as color images. A set of tools allows for measurements and annotations to be applied to the images. The CD-ROM also contains a short description of the program and it's features as well as a series of links to web sites where more detailed instructions and information are available. The OSIRIS software being constantly upgraded, a link to the web site is provided to allow users to download the latest version of the software if needed.

Documents and reports: all documents and reports associated with the images are converted and stored in HTML format to be directly displayable within a web browser. Pages with a list of the documents are also generated and hyperlinks are set to automatically retrieve the corresponding report or clinical documents.

WebPages and information: The CD-ROM also contains additional web pages that can be specifically related to the images and data contained on the CD. For example if the CD contains MR or CT images, general information about these procedures

are included on the CD. Additional guidelines and information are added for specific areas such as cardiovascular or oncology. These pages also contain hyperlinks to specific web sites that may host additional sources of information.

3. RESULTS

The system allows to automatically receive and sort images and data files of a specific patient and store them in a formatted CD-ROM with all the associated files that are needed to support these data files. The disks can either be a standard 4 3/4" CD-ROM with 650 MB capacity or even small 3" CDs with 250 MB capacity. The same system could also generate DVD when recordable DVDs become more widely available.

Figure 2: Sample CD with patient identification and label of the content of the disk, the disk is self-bootable on both Windows and Macintosh platforms

The disks generated are "self-bootable" on both Macintosh and Window platforms. As soon as the disk is inserted in a CD drive, and as long as the computer is equipped with a standard Web-browser software, the user is automatically prompted with a web page that shows a cover page with the patient identification (see figure 3).

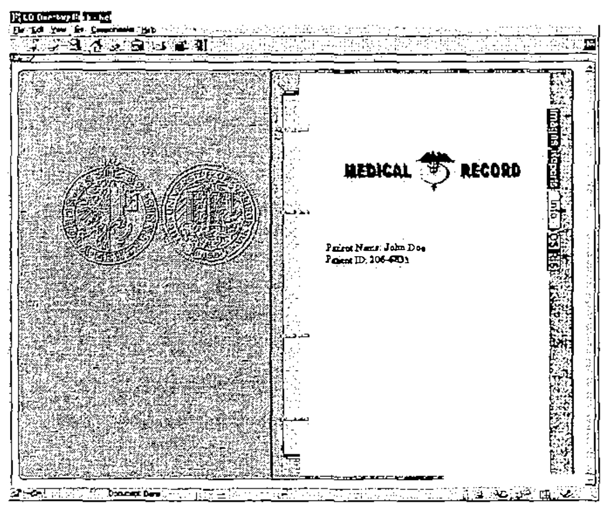

Figure 3: The first page presented to the user is an HTML cover page with patient identification and side tabs that allow to check the content of the disk

This first home page is designed in the format of a notebook with side-tabs linking to additional pages listing the content of the disk. Typically the content is divided in four sections:

- The list of image files
- The list of corresponding reports and documents
- A list of information documents and guidelines
- A set of guidelines on the usage of the OSIRIS viewer

Each section corresponds to a separate HTML page with a list of hyperlinks to the documents that are stored in the CD-ROM. These lists are presented together with thumbnail images when appropriate for easy selection of the images to be reviewed.

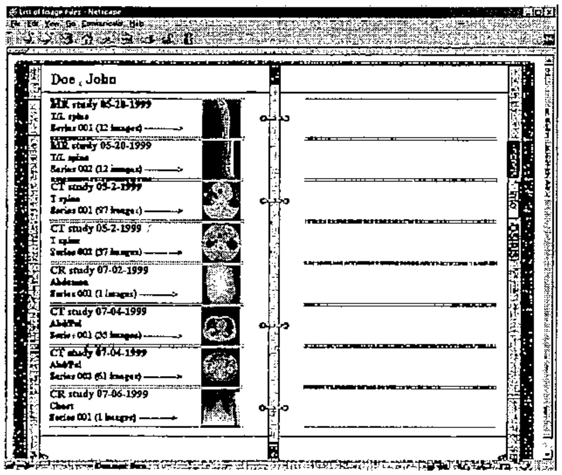

Figure 4: The image files contained in the disk are listed in chronological order with a thumbnail image representative of the content of the file.

The list of image files is presented with minified thumbnail images. Clicking one of those thumbnail images will display a separate page with the complete list of images in that file (see figure 5). The user can then select any image to display a full size JPEG image directly in the same browser page.

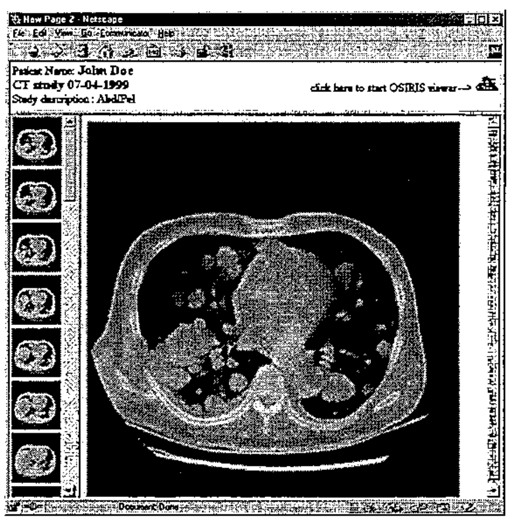

Figure 5: By selecting an image file from the list will display a page with the complete list of images in the file that can also be displayed in full-size JPEG-compressed image

All the images are also stored in their native DICOM format at full resolution. A link is provided to lunch the OSIRIS viewer to display these images with all windowing and zooming capabilities. The DICOM files stored on the CD-ROM can also be displayed by any DICOM-compliant software or diagnostic workstation. The file format is confonnant with "off-line" storage rules described in chapter 10 of the DICOM standard. That includes a DICOMDIR file stored in the root directory that includes references to all DICOM files stored on the disk. Most DICOM viewing software capable of reading CD-ROMs will look for the DIOCOMDIR file to retrieve images from the disk. The disks that we generated were tested on several commercial platforms as well as on public-domain software programs and without any major difficulty.

4. DISCUSSION AND CONCLUSIONS

The idea of storing medical images on portable media such as a CD-ROM is not new, and has been promoted by several different projects and initiatives even before the advent of the DICOM 3.0 standard. One of the most known initiative is the one proposed in Japan under the name of ISAC (Image Save And Carry). The development of the DICOM standard has added a broader scope being an internationally adopted standard. The concept of exchanging images through CD-ROMs has been widely adopted by the cardiology community for the communication of X-ray angiogram images. This concept is now also being promoted by some vendors for images from other imaging modalities as well.

The use of off-line CD-ROMs for the exchange of medical images in DICOM format has always suffered from the lack of easily accessible image viewers that can be used on personal computers. Public domain programs such as OSIRIS are available on web servers and can be downloaded from the Internet, but most physicians will still find it cumbersome to retrieve and install a software to be able to review a patient's CD-ROM. We therefore strongly believe that adding the image viewer directly on the CD will greatly facilitate the wider adoption of such a solution for convenient exchange of patient records between different healthcare providers.

Furthermore, by adding HTML pages that can be automatically displayed in any Web-browser program adds a degree of convenience and ease of use for non-computer savvy users. It allows to easily review the content of the disk and select the images and document to be reviewed. This techniques also allows to conveniently add other relevant documents such as clinical reports, infonnation to referring physicians, guidelines and general information to the patients etc.

This portable solution provides a convenient and low cost alternative to hard copy films for exchange and transmission of images to referring physicians and external care providers. It also provides a convenient way to provide patients with an access to their medical record together with specific information and guidelines.

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Version 1.9

User's Guide

DICOMview
CardiacNetwork

Desktop Angiographic Review Software
Workgroup Edition

DEFENDANT'S EXHIBIT 202

Exhibit 202

Table of Contents

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PG024610

Chapter 1

Introduction

PG024611

1.1 A Brief History of the DICOM Standard[1]

Digital storage and exchange of cardiac images has much to offer physicians and patients, including remote viewing of images, random access within studies, improved quantitation, and transmission of high-quality images to other institutions. There continues to be a proliferation of digital technologies within the cardiac catheterization lab, as well as with other cardiac imaging modalities (such as echocardiography, nuclear, etc.). Despite continued efforts to move from cine film to all-digital approaches, there has to date not been adequate means for exchanging images between institutions in digital formats. Whatever limitations exist for cine film, it remains a universal medium, and one that can be viewed anywhere in the world. Until similar capabilities exist for digital studies, the goal of the filmless cardiac catheterization lab cannot be realized.

The National Electrical Manufacturers' Association (NEMA) and the American College of Radiology (ACR) began work in 1982 on developing a standard for the digital exchange of medical images. The resulting ACR/NEMA standard was first released in 1985, and subsequently revised in 1988. In the most recent release, the standard has been renamed to "Digital Imaging and Communications in Medicine" (DICOM). This standard extends the earlier ACR/NEMA work in several ways, using industry standard networking protocols, specifying mechanisms for image storage on removable media, adding additional imaging modalities, and including information about services to be performed on the data. As the major image standard for medicine, DICOM is therefore a key component to be addressed within the broader concept of the Computerized Patient Record.

PG024612

1 Large portions of this introduction were extracted from the paper "DICOM Media Interchange Standards for Cardiology: Initial Interoperability Demonstration" by Jonathan L. Elion MD, FACC of the Brown University Institute for Medical Computing, Providence, RI

The American College of Cardiology (ACC) has been working with NEMA and ACR to help refine standards for the digital storage and interchange of cardiac images since 1992. The initial effort was for x-ray angiography, with a parallel effort coordinated through the American Society of Echocardiography for cardiac ultrasound. A strong emphasis of this effort has been standards for exchanging images on removable media.

1.2 Why DICOMview®?

DICOMview® was developed to realize the potential of digital image interchange via the DICOM standard with powerful new software based on the computer industry's most user-friendly operating systems--MacOS, Windows 95, and Windows NT. DICOMview® is compatible with all major vendor's DICOM interchange systems including Philip's CD Medical and GE's GEMnet.

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Chapter 2

Getting Started

PG024614

2.1 Hardware Requirements/Recommendations

The following are PC computer hardware specifications which are required for running DICOMview®.

Pentium or Pentium Pro processor
Windows 95 or Windows NT 4.0
32 MB RAM
1 GB hard disk
16 inch display (800x600)
4x CD-ROM reader

We strongly recommend that your system(s) have the following specifications:

Pentium II processor or faster
64 MB of RAM or more
12x CD-ROM reader
SCSI controller and SCSI hard drive
17 inch or larger display (1024x768)
Network (Required for workgroup features)
SVGA board capable of True Color at 1024x768

2.2 Installation

See the installation instructions accompanying the distribution media.

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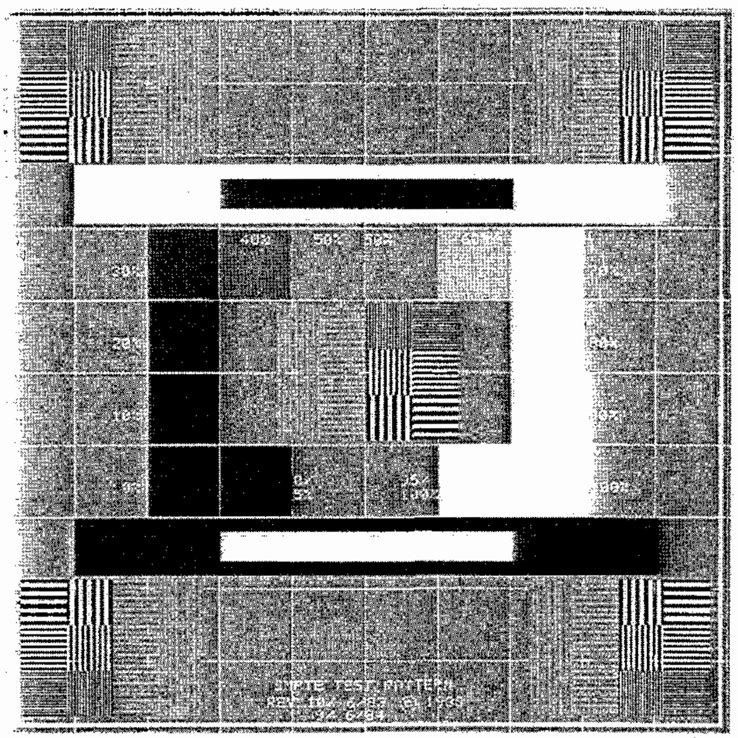
2.3 Adjusting your monitor

To assist you in adjusting your monitor for optimal image quality DICOMview® can display a SMPTE test pattern. This image can be displayed by selecting the **Calibrate Monitors** item from the **File** menu. This test pattern appears as follows:



2.3.1 Adjust Monitor Brightness/Contrast.

Good contrast is an important component of image quality. The center region of the SMPTE test pattern contains gray shaded blocks that progress from 0% saturation (black) to 100% saturation (white). Adjust your monitors brightness and contrast until you can distinguish the difference between the adjacent 10% gradients.

2.3.2 Adjust Monitor Horizontal and Vertical Convergence.

Convergence is especially important if you are using a color display. Color displays utilize three colors red, green and blue to make colors and shades of Grey. A properly adjusted monitor will allow you to clearly see the horizontal and vertical lines in the center and four corners of the test image. Many modern monitors allow the user to adjust convergence. If your monitor is not properly aligned and it does not include an adjustment, seek assistance from the display manufacturer.

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Chapter 3

DICOMview® General Features

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3.1 DICOMview® General Features

The following list outlines the general features and advantages of the DICOMview® software:

- Workstation-level performance on mid-range PC or PowerPC desktop systems.
- Playback of 512x512 images at up to 100 FPS. Continuous pan and zoom.
- Brightness. contrast, gamma and shuttle controls.
- User friendly button-bar providing quick access to all features.
- Tool-tips displaying quick hints for major functions.
- Review images directly from all standard DICOM CDs and OEC Jaz Cartridges.
- Optional Left Ventricular and Quantitative Coronary Analysis.
- Local DICOM database permitting fast review of studies from local or network storage devices.
- Windows savvy application coexisting with all Windows applications.
- Exports still images directly to word-processing, presentation, graphics and desktop publishing software.
- Prints to any printer including postscript and color printers.
- Saves a cine-loop as an AVI movie for use in multimedia presentations.
- Optional DICOM CD mastering.
- Optional jog wheel controller.

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Chapter 4

Using DICOMview®

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4.1 Starting DICOMview®

Start the DICOMview® program by double-clicking on the DICOMview® icon (Figure 1). Or you may select it from your Windows **Start** menu.

Figure 1. DICOMview® icon.

You will be presented with a menu bar that includes DICOMview® and standard Windows functions. You will also see a button-bar that allows fast, easy access to the DICOMview® and file access functions.

4.2 The DICOMview® Menu Bar

The DICOMview® menu bar appears at the top of the window as in other Windows programs (Figure 2).

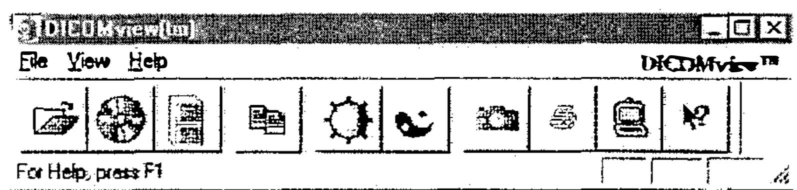


Figure 2. DICOMview® menu bar.

Many of the functions that appear in these menus (particularly the File and Edit menus) are standard Windows functions. In addition, many of the functions in these menus can be more quickly and easily accessed using the button-bar directly below the menu bar (see next section). Those functions which also appear in the button-bar have the corresponding icon from the button-bar with the function in the menu and are indicated with a * in the tables below. The functions in the File, View, Image, and Window menus are described in Tables 1 through 3 (all of the functions in the Edit and Help menus are standard Windows functions).

Table 1. The File Menu

Function	Description
Open Study	Open a cardiac study from any available source media. The Open Study Dialog presents a list of available DICOM, Heartlab Preload (local and network drives), Enterprise Database, and OEC sources. The last used source media is selected. Choose the desired source as needed. Press the SHOW button and choose your study from the list.
* Open CD-ROM Study...	Open a cardiac study from a CD-ROM. A list of files will be presented from which to choose a study. Click on the desired study and then click on Open (or double click on the study). A "list" of small images will appear along the left side of the screen; each image represents an image sequence in the study. Double click on one of the small images to load that sequence off of the CD-ROM. The sequence may play at less than its acquisition rate the first time through since the frames are being loaded off the CD and are also being decompressed. Once the image is loaded, the sequence will play at the rate at which it was captured.
* Copy Study...	Copy one or more studies from the any source to any destination. When this function is selected, a list of studies will be presented. Select as many or as few as desired by clicking/holding down the mouse button then dragging the cursor over the studies. Choose the destination media from the destination media list. Then select **Copy**. The copying of images can take a while depending on how many studies were selected (more studies = more time). If a CD writer is chosen as the destination, you will be given a chance to change the patient's name and birth date before writing the CD.
* Open Preloaded Study...	Open a Preloaded study from the hard drive. When Open Preloaded is selected, a list of studies from the last used preload index will be presented. Select the desired preload source in the source media list. Click on a study and then click on Open (or double click on the study). A "list" of small images will appear along the left side of the screen; each image represents an image sequence in the study. Double click on one of the small images to load that sequence off of the hard drive. The sequence may play slower than its acquisition rate the first time through since the frames are being loaded off the hard drive and are also being decompressed. Once the image is loaded, the sequence will play at the rate at which it was captured.
Close	Closes the current image sequence window (but not the current study). Does not exit the program.
* Save as Bitmap	Saves the current (paused) image frame to a BMP file. When this option is selected, the standard Windows file save dialogue box will pop up for entry of the file name/location. This file can then be imported into word processing or graphics software. This BMP format contains data which is identical to the original DICOM image.

PG024621

Save as AVI Movie	Save the current sequence as a AVI movie. You will be presented with a dialog box from which to choose save options. The AVI format may degrade the quality of the data. ***AVI is intended for presentations or other documentation and not for primary diagnosis.***
Preferences	Allows the user to set several application options.
Calibrate Monitors	Displays SMPTE test pattern in all active displays. Use this to adjust the brightness and contrast of your monitor for optimal image quality.
* Print...	Print current frame to the selected printer. Printing is provided for presentation and other documentation and is not intended for primary diagnosis.
Print Preview	This is the standard Windows Print Preview dialogue box for previewing the image before printing.
Print Setup...	This is the sta dard Windows Page Setup dialogue box for setting up a page for printing.
Exit	Closes all opened files and exits the program.

Table 2. The Edit Menu.

Function	Description
Copy	Copies th paus d image into the Windows clipboard as a Windows bitmap

Table 3. The View Menu.

Function	Description
Toolbar	Hide or view the toolbar
Analysis Toolbar	Hide or view the analysis toolbar
Status Bar	Hide or view the status bar (bottom of screen)
Laptop mode	Rearrange the screen for better viewing at 800x600 display resolution
Window Positions	Choose and set default positions for image viewing windows

Table 4. The Sequence Menu (enabled when the image is viewed).

Function	Description
Play	Play (or resume playing) the current image sequence
Stop	Stop the current image sequence from playing (pause sequence)
Frame Forward	Advance a paused image by one frame
Frame Backward	Reverse a paused image by one frame

PG024622

Table 5. The Image Menu.	
Function	Description
* Color Shuttle	If the menu selection reads "Show Color Shuttle", this function pops up controllers for brightness and contrast of the images in the sequence. These controllers also look and work just like scroll bars. If "Hide Color Shuttle" is displayed, this function will make the brightness and contrast controllers disappear.
* Invert Colors	Inverts the color mapping of the images in the sequence (white to black and black to white).
Zoom Out	Zoom out (shrink) the current image sequence
Zoom In	Zoom in (enlarge) the current image sequence

Table 6. The Analysis Menu (enabled when the image is viewed).	
Function	Description
Calibrate	Enter the image size calibration mode of analysis.
LV Analysis	Enter the LVA mode of analysis.
LV Analysis Details	Display the LVA mode sub-menu.
Calipers	Enter the calipers mode of analysis.
Calipers Details	Display the calipers mode sub-menu.
Stenosis	Enter the stenosis mode of analysis.
Stenosis Details	Display the stenosis mode sub-menu.

Note: the analysis menu is available when purchased as a DICOMview® option.

Table 7. The Pie Medical Menu (enabled when the image is viewed).	
Function	Description
Open Frame Selection	Open the Pie Medical Frame Selection Dialog. This allows selection of still frame images for export from DICOMview® to Pie Medical's CAAS II LVA and QCA analysis packages.

Note: the Pie Medical Menu is available when licensed as a DICOMview® option

Table 8. The Window Menu.	
Function	Description
Cascade	Arrange the open DICOMview® windows in a cascaded fashion.
Tile	Arrange the open DICOMview® windows in a tiled fashion.
Arrange Icons	Arrange all minimized DICOMview® windows along the bottom of the screen
Window 1..	Allows selection of open DICOMview® windows

PG024623

Table 9: The Help Menu.	
Function	Description
Help Topics	Access on line help for DICOMview®
Licensing	Display DICOMview® licensing information
About DICOMview	Display DICOMview® version information

4.3 The DICOMview® Button-Bar

The DICOMview® button-bar allows fast, easy access to the DICOMview® and file access functions. This button-bar will appear upon launching of the DICOMview® software (Figure 3). All of the functions in this button-bar are also available through the menus at the top of the screen, but you will probably find the button-bar to be far more convenient to use.

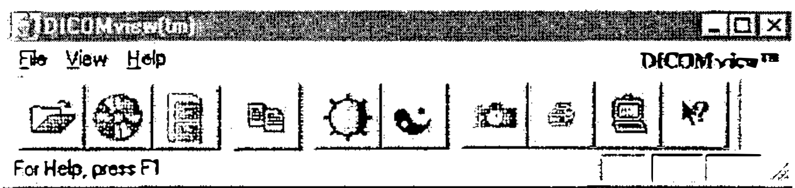
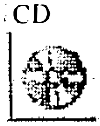


Figure 3. DICOMview® button-bar.

The functions of the icons on the button-bar are described in Table 5.

Table 5: DICOMview® Button-Bar Functions		
Icon	Function	Description
Folder 	Open study	Open studies from any source media
CD 	Open File (from CD)	Opens a cardiac study from the CD-ROM drive. Same as the folder but "pre" selects a DICOM CD source media
File Cabinet 	Open Preload File (from Preloaded images)	Opens a cardiac study that resides on the hard drive. Same as the folder but "pre" selects a preload source media.
Copy Study 	Copy Study	Copy cardiac studies from any source to any destination.

PG024624

Color Control 	Show Brightness/Contrast Controllers	Pops up controllers for brightness and contrast of the images in the sequence.
Yin/Yang 	Invert Image	Inverts the color mapping of the images in the sequence (white to black and black to white)
Camera 	Grab Still Picture of Frame	Saves a picture of the current (paused) frame to a Bitmap format file
Printer 	Print Frame	Sends the current (paused) frame to the currently selected printer
Lap Top Mode 	Switch Lap Top Mode on or off	Lap Top Mode sets the DICOMview screen layout to the optima settings for viewing on smaller monitors, typical on laptop computers
Help 	Context sensitive help	Click on this button, and then click on any another control button to display help on that item.

If the cursor is positioned over a button on the button-bar, a hint on how to use that button appears as a standard Windows ToolTip. Hints will also appear in the status bar at the bottom of the application window if the status bar is enabled.

4.4 Working with DICOM media

DICOMview® provides some flexible options when working with DICOM interchange media. This section describes how DICOMview® treats removable media such as CD's and how to manage your own local image directory. Understanding how to manage these storage options will help you get the most out of this powerful software.

4.4.1 Removable media

DICOMview® was designed to work with the DICOM standard compact disc recordable (CD-Rs) for interchange of angiographic x-ray images. To load a CD-R into your system follow these easy steps:

1. Eject the existing CD-R if it exists. Remember to close any studies open from the CD-R before you eject it.

2. Load a new CD.

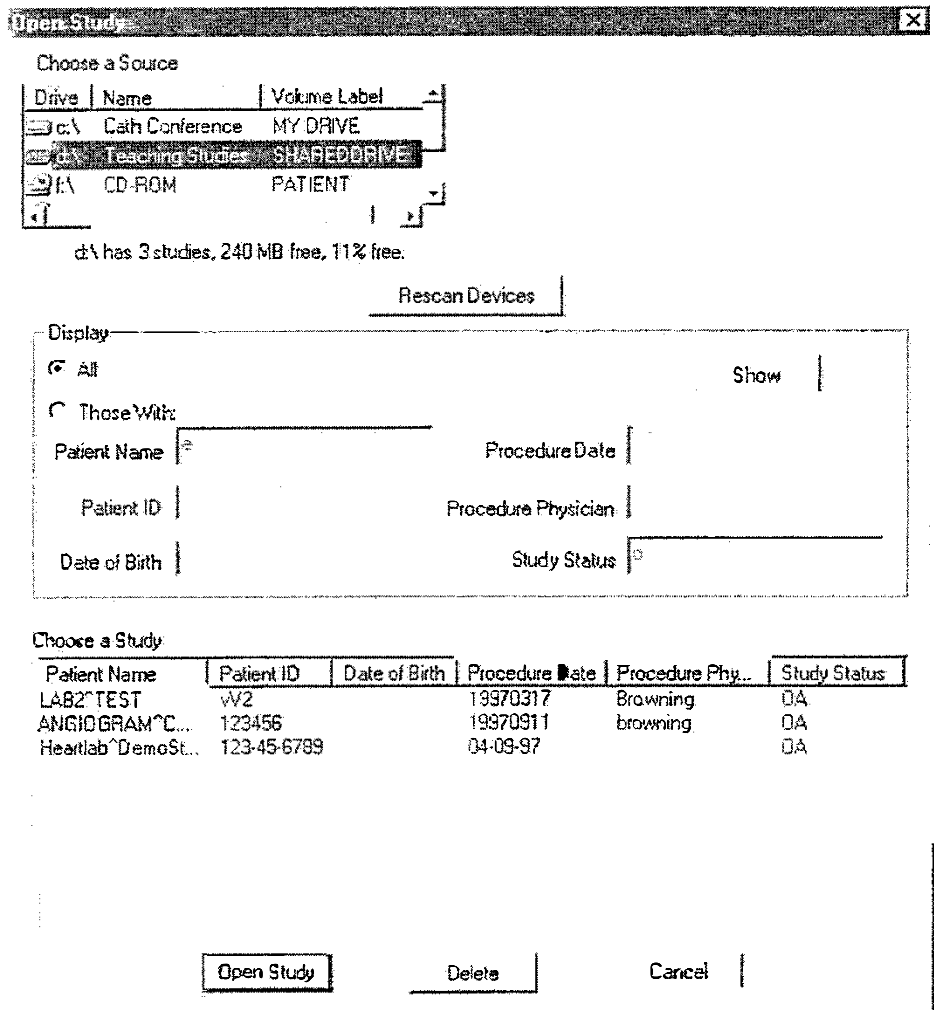
Insert the new CD into the drive and push the drive door closed.

At this point you may browse the contents of the CD and review studies directly from the CD or copy studies directly to you local DICOM directory. For information on managing your local directly see section: 4.3.2 Local DICOM Directory.

3. Open the CD-R DICOM directory.

To browse the contents of the CD-R click on the CD button (in the button bar) or select Open Study... from the **File** menu. You will see a dialog box similar to this:

PG024626



For More Information on loading studies see section **4.5 Working with Studies.**

The following table describes the searching capability of DICOMview®. You can search using any combination of fields. Enter your search criteria in any of the search fields shown above and press the Show button.

Partial entries are matched. For example: searching for **Jo** in the last name field would return a listing of studies for all patients with last name Johnson, Johann, Joseph, etc. Searching for 194 in the Date of birth field would return all patients born in the 1940s.

PG024627

Search Field	Usage
Patient Name	Lists studies for all matching names.
Patient ID	List studies for matching patient ID.
Date of Birth	Patient DOB entered in cath lab.
Procedure Date	Date study was performed.
Procedure Physician	Physician name entered at the cath lab console at the time of study acquisition.
Study Status.	Shows "A" if a preloaded study also appears on a CD.

4.4.2 Local or Network Preload Directory

One of the most powerful features of DICOMview® is its ability to maintain a "Preload" directory of DICOM images on the hard-disk of a PC. The disk may be on your local computer or it may be a shared network disk. A simple dialogue allows the user to manage the contents of this directory.

IMPORTANT: Only one directory is permitted per hard-drive. Select a fast hard-drive with a large amount of free space.

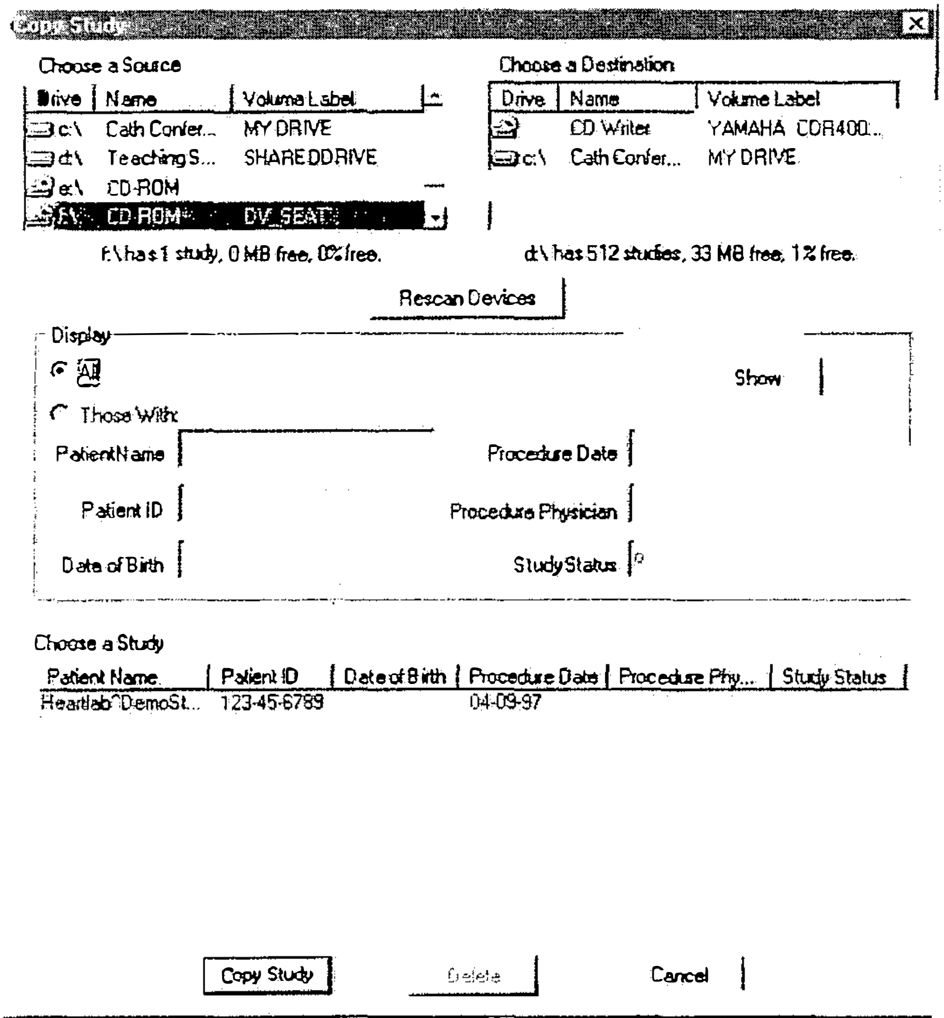
4.4.2.1 Adding Studies to Your Local or Network Directory

Studies are added to your Preload directory by copying them from DICOM interchange media using the **Copy Study...** option in the **File** menu. The following steps are used to load images to your local directory:

1. Insert the DICOM CD-R.
Insert the CD-R and mount the DICOM media. (For a description of this process see **4.4.1 Removable Media.**)

2. Select Copy Study...
Select **Copy Study...** and the following dialog will appear:

PG024628

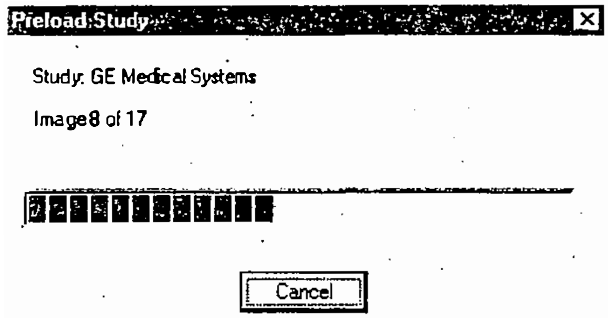


NOTE: If you exchanged media while this dialog was up, just press **Rescan Devices** to refresh the source and destination lists.

3. Select the source and destinations for the Preload operation. You may Preload directly from the CD or may load studies from one Preload index to another.

Select one or more studies from the list and press the **Copy Study** button. The following progress dialog will be displayed:

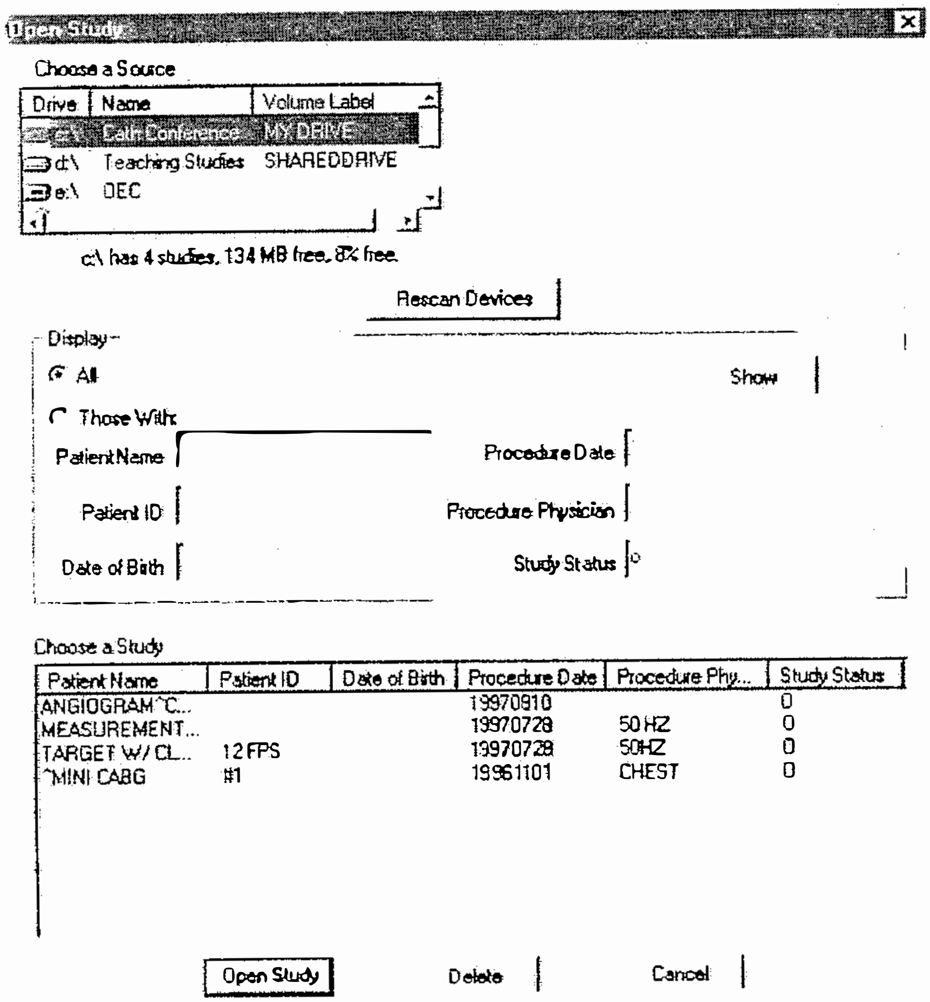
PG024629



When the study has been loaded the dialog will vanish and the study will be added to the destination preload directory.

4.4.2.2 Loading and Deleting Studies from Your Local Directory

Access to your local directory is gained by clicking on the filing cabinet icon or selecting **Open Preloaded Study...** from the **File** menu. This will popup a dialog similar to the one depicted below:



To open a study select the **Source** and any **Display : Search Options** you wish to search on then press the **Show** button (**See Section 4.4 Working with Studies**). If you wish to display all the studies on the media or hard-drive click on the **All** radio button and then click on **Show**. To delete a study, highlight the study and press the **Delete** button. This will remove the study from your local directory.

PG024631

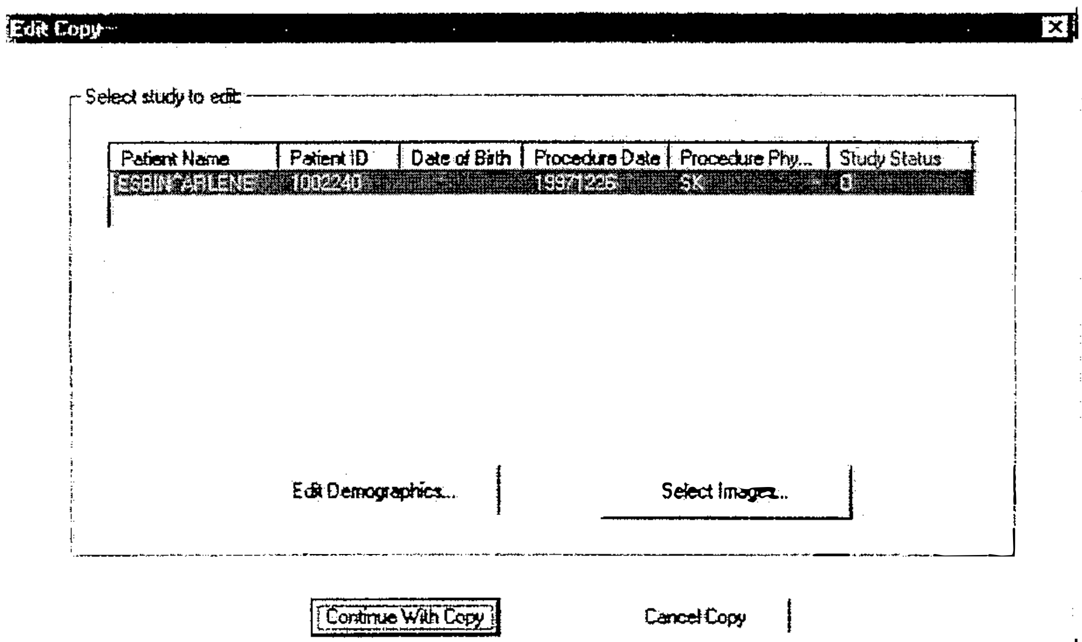
4.5 Working with Studies

Reviewing studies from DICOM media or local/network Preload directories is easy with DICOMview®. This section helps you work with the DICOMview® study dialogs. To review a study, first select its source (see previous sections).

4.5.1 Copying Studies

The Copy Study dialog allows you to copy any number of studies from any listed source to any listed destination. The **Copy** button will copy all images in the selected series from the selected source to the selected destination.

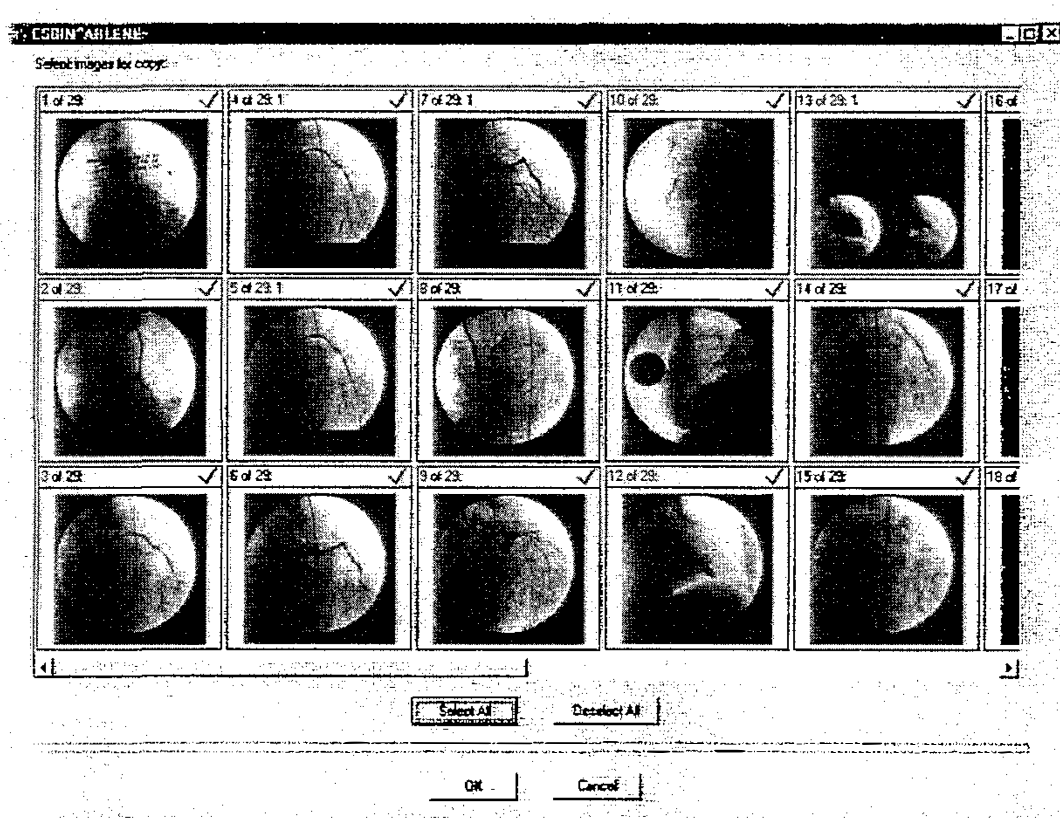
The **Copy with Edit** button will bring up the Edit Copy Dialog.



If the destination is a CD writer, the **Edit Demographics** button will be enabled. Pressing this button will allow you to change the patient's name and date of birth on the destination CD. The original study will carry the original name and date of birth.

PG024632

Pressing Select Images will bring up a dialog allowing you to select one or more (or all) images for copy to the selected destination.



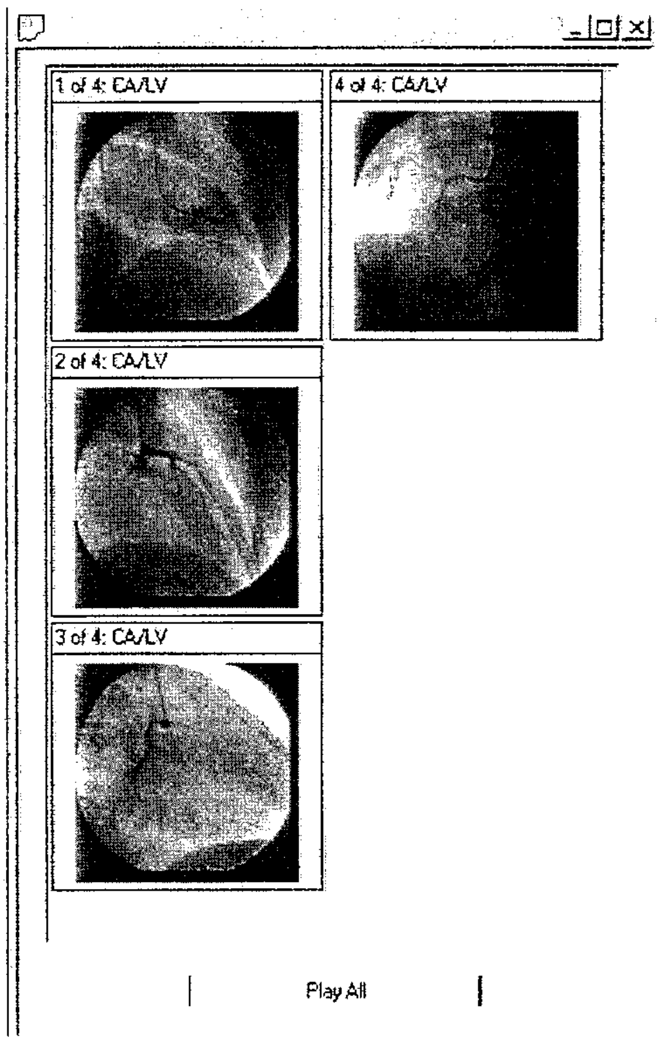
Use the **Select All** and **Deselect All** buttons or click directly on the thumbnail images to select specific images for the copy. Press OK to accept the current selections or Cancel to revert to the last selected set of images.

On the Edit Copy Dialog, you may then select **Continue with Copy** or **Cancel Copy**. If you select Cancel, no images will be copied.

PG024633

4.5.2 Reviewing Studies

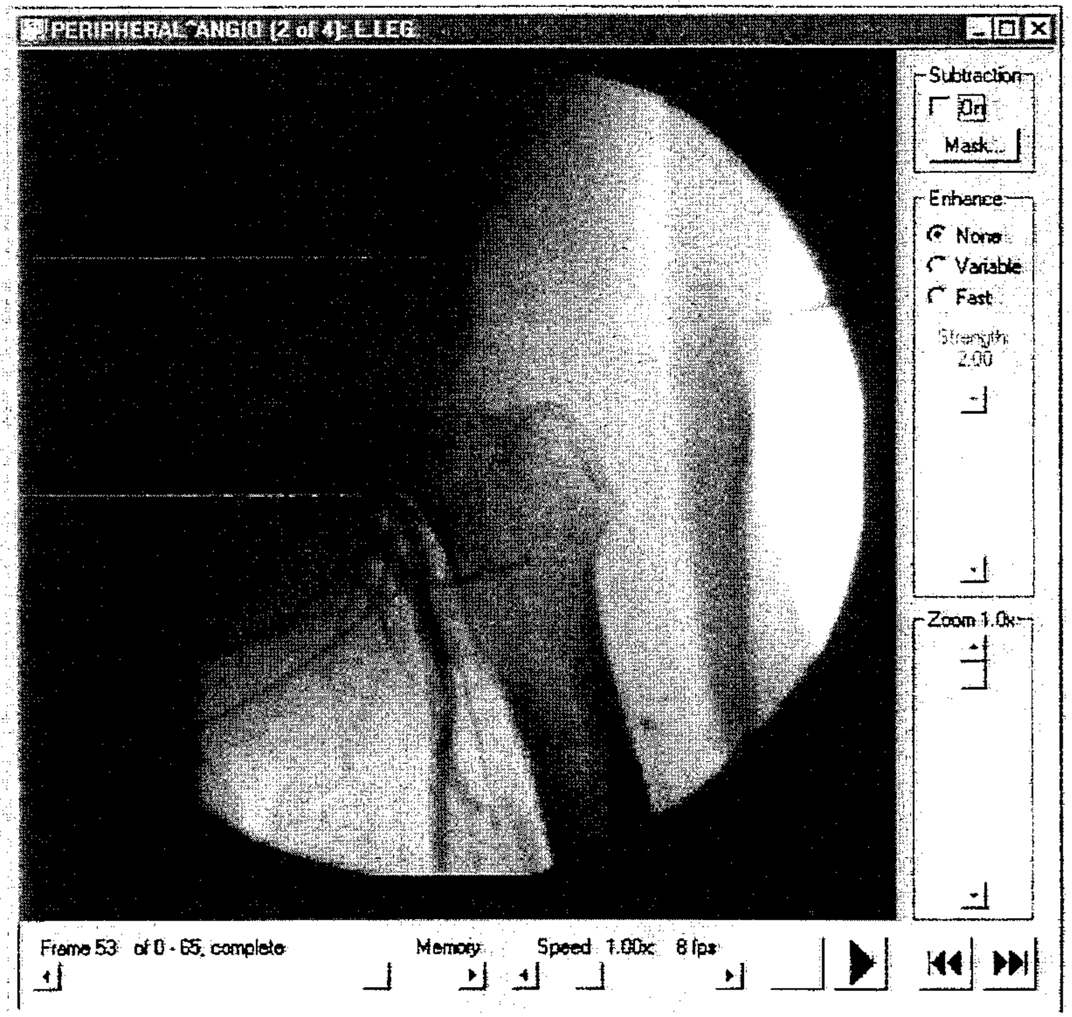
To review a study highlight the study of interest by clicking on it with the mouse and click on the Open button. This will cause the Open Study dialog to vanish and will load the study thumbnails. At this point your screen will have the image thumbnail navigator present:



To review a study "double click" on the thumbnail image that corresponds to the cine-loop which you would like to review.

PG02634

Once you have opened the sequence it will immediately begin playing. The image window will look like this:



PG024635

Some Important information is displayed on the image window. The following table describes this information:

Information	Description
Frame Shuttle	The scroll bar allows you to shuttle between individual frames of the injection sequence. Above the scroll bar is an indication of the frame number currently being displayed and from what source it will ultimately play from, either media (CD-R or hard-disk) or memory (RAM). The starting and end frame being played is also displayed, which indicates whether the whole im ge sequence has been fit into memory. See the preferences section for detailed information on controlling what percentage of the imaging sequence should be played from memory.
Speed Shuttle	Current Playback Speed Fact●r: When the image has been loaded it will play back at a rate equ l to: (acquisition rate * speed factor). For example an image acquired at 30 frames/second (FPS) would playback at 30 FPS with Speed = 1x and 60 FPS with speed = 2x. General acquisition rates are 15 FPS and 30 FPS.
Stop Control	Stop current playback.
Play Control	Play the injection sequence.
Previous	Play the previous injection sequence.
Next	Play the next injection sequence in order.
Zoom Shuttle	Continuously zoom in or out from the image by adjusting the Zoom shuttle bar.
Subtraction	Turn Digital Subtraction on and off. Launch the Subtraction Mask dialog.
Enhancement Controls	DICOMview® can perform edge detection (sharpening) on the image being played. You may turn enhancement on by clicking the appropriate radio button for variable or fixed strength enhancement. Fixed strength is faster but cannot be varied with the strength slider.

4.5.3 Reviewing a Study (Play ALL Mode)

DICOMview® provides two ways of reviewing a study. The first method **Study Mode** permits you to browse thumbnails and select specific cine-loops for review. The second method **Play ALL Mode** allows you to review the entire study from end to end (exam mode). This mode simulates a film projector. To open a study in exam mode press the **Play All** button on the thumbnail navigator.

PG024636

4.5.4 Reviewing Multiple Cine-loops

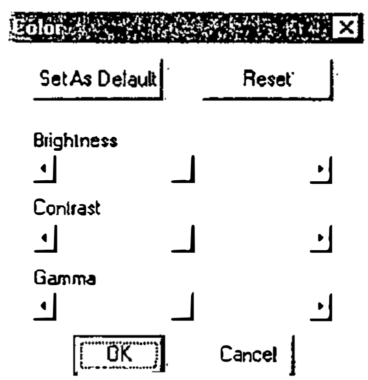
DICOMview® allows you to open several cine-loops simultaneously. To open a second window just double click on the thumbnail image of the sequence you want to see. This will cause each cine-loop you select to be opened into a new display window. You can adjust the placement of the windows to view the image side-by-side.

4.6 Controlling Sequences

Sequences can be controlled in a variety of ways. The basic sequence controls for **Stop, Play, Frame Forward, Frame Backwards** can be found in the **Sequence** menu. The image window also contains controls for **Stop** , **Play** and **Frame Forward, Frame Backwards Shuttle** controls. The image window also contains a **Previous** and **Next** control to move between cine-loops of the full study.

4.7 Adjusting Images

Image brightness, contrast, and gamma can be adjusted using the color shuttle dialog. This dialog is popped up when the **Color Shuttle...** option is selected from the **Image** menu or for the button bar. This dialog is depicted below:



The **Reset** button restores the brightness, contrast, and gamma to their default settings. The image may be inverted (white arteries on a black background) by pressing the Yin/Yang button on the button bar or choosing **Invert Colors** from the **Image** menu.

4.8 Enhancing Images

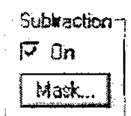
Image enhancement (sharpening) is provided in the form of a convolution based edge enhancement algorithm. To use this feature click on the **Variable** or **Fixed** radio button in the image window.

These controls enable enhancement on the image being processed. When **Variable** is selected the enhancement strength can be adjusted. Increasing the strength sharpens edges in the image but also increases the amount of noise. When **Fixed** is selected, enhancement uses a pre-computed algorithm that is faster but does not have variable strength. Hence the **Strength** slider is disabled when in **Fixed** edge enhancement mode.

4.8.1 Digital Subtraction

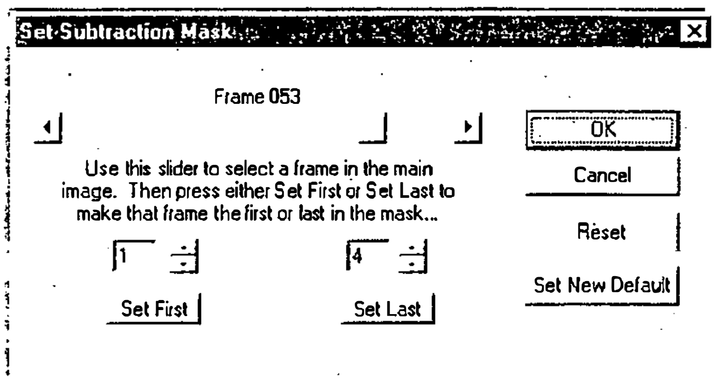
Digital Subtraction is a useful image processing function that effectively removes or subtracts part of an image. Typically, anatomy such as bones or tissue that are not clinically relevant will be specified as the "subtraction mask". The mask is the part of the image which is taken away during the subtraction image processing. The resulting picture will feature the anatomy that is revealed during the dye injection (typically vascular anatomy).

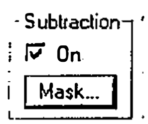
To set or change the mask, press the Mask... button.



PG024638

Use this dialog to set the subtraction mask. In this example, the user has chosen to average frames 1 – 4 to obtain the mask. Use the frame slider to view a frame in the main image window, then press "Set First" or "Set Last" to set the first and last frames of averaging. Press OK to average the frames together to set the mask.





The On checkbox (upper right of image window) tells DICOMview® whether or not to perform subtraction on the current image.

PG024639

4.9 Lap Top Mode

A display screen of size 1024x768 pixels or more is best for viewing DICOMview® images. This larger size screen allows for displaying entire image views in a non-maximized state. An 800x600 screen can also be used for viewing DICOMview® images, however, in order to see the entire image view you should select the Lap Top Mode.

 Selecting the Lap Top Mode does the following:

Maximizes the DICOMview® application window.
Maximizes the DICOMview® child window.
Docks the toolbar on the right side.
Hides the status bar.
Requests you to select the auto hide mode for the taskbar if it will be required to view the image area.

If your screen is an 800x600 pixel screen, you will need to select the auto hide feature for the system taskbar in order to see the entire image view. The system taskbar is the bar that contains the **Start** button. It typically appears at the bottom of the display screen. To select the auto hide feature, do the following:

Place the cursor over an empty area on the taskbar.
Press the right mouse button and select **Properties**.
Check the auto hide check box.
Press the dialog's **OK** or **Apply** button.

The taskbar will be hidden until you move the cursor near the edge where the taskbar normally appears. As you approach the edge, the taskbar will appear.

If you unmaximize the application or the child window while in the Lap Top Mode, it will remain unmaximized in the Lap Top Mode until you maximize the window yourself or until you re-enter the Lap Top Mode. Re-entering the Lap Top Mode always maximizes the application window and its child window.

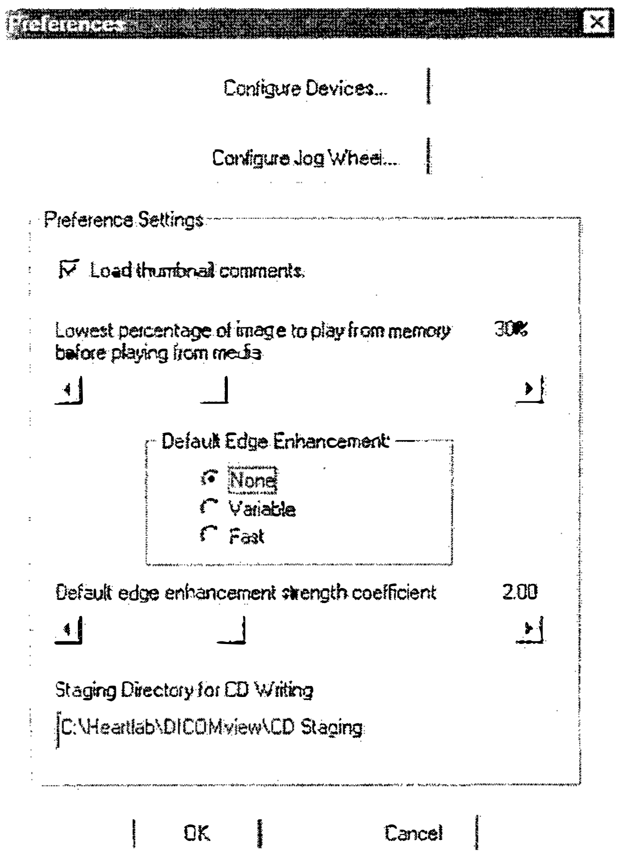
If you undock the toolbar or re-dock it on another side of the application while in the Lap Top Mode, it will remain it that position while in the Lap Top Mode until you re-dock it or move it. Re-entering the Lap Top Mode will not re-dock it on the right side. This allows you to tailor the Lap Top Mode to your needs.

If you enable the status bar while you are in the Lap Top Mode, it will remain enabled in the Lap Top Mode until you hide it using the Status Bar command. Re-entering the Lap Top Mode will not hide it. This allows you to tailor the Lap Top Mode to your needs.

PG024640

4.10 Preferences

Selecting Preferences... from the **File** menu will display the following Preferences dialogue window:



PG024641

The following table describes DICOMview® preferences.

Preference	Description
Load thumbnail comments	Enables loading of image comments from the image files when displaying thumbnails from the DICOMDIR. Applies to CD review only.
Lowest percentage of image to play from memory before playing from media.	When memory is low this setting allows the user to determine how much of the cine loop will be displayed from fast memory. The central portion of the loop is displayed. If this minimum percentage of the loop can not be displayed the entire loop will play directly from the media.
Default edge enhancement	Automatically set edge enhancement to None, Variable, or Fast when playing images.
Default edge enhancement strength coefficient	When enabling Enhancement from the image window, the default strength of the enhancement algorithm will be the value you set in this preference shuttle.
Staging directory for CD Writing	User defined location for temporary files produced in the CD Writing process.

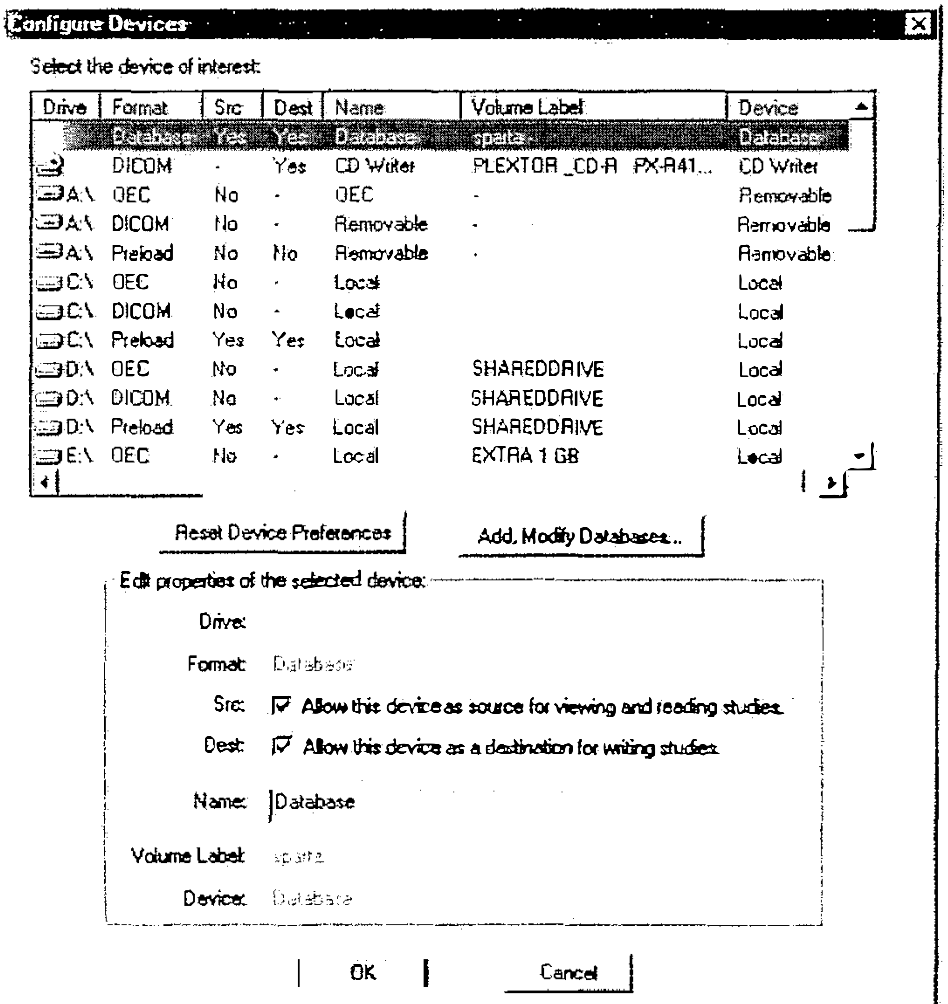
4.10.1 Configure Devices

Use the Configure Devices dialog to select the devices you wish to appear on the Open Study dialog box as source and destination devices. You may also specify your own name for each device.

All devices available to DICOMview® are listed on this dialog. Each device listed represents a unique combination of a particular physical device, and a particular data format. For example, there may be three device entries for the local disk "C:\", one for the Preload format, one for the DICOM format, and one for OEC format. Some of these devices may represent unlikely combinations of physical devices and formats, e.g., DICOM format on a floppy drive. However, all devices are included for completeness. Unlikely devices are defaulted to a disabled state.

You can display this dialog using the Configure Devices button on the Preference dialog.

PG024642


Configure Devices
Select the device of interest:
Drive Format Src Dest Name Volume Label Device
Database Yes Yes Database sparta Database
DICOM - Yes CD Writer PLEXTOR CD-R PX-R41... CD Writer
A:\ OEC No - OEC - Removable
A:\ DICOM No - Removable - Removable
A:\ Preload No No Removable - Removable
C:\ OEC No - Local Local
C:\ DICOM No - Local Local
C:\ Preload Yes Yes Local Local
D:\ OEC No - Local SHAREDDRIVE Local
D:\ DICOM No - Local SHAREDDRIVE Local
D:\ Preload Yes Yes Local SHAREDDRIVE Local
E:\ OEC No - Local EXTRA 1 GB Local
Reset Device Preferences
Add, Modify Databases...
Edit properties of the selected device:
Drive:
Format: Database
Src: Allow this device as source for viewing and reading studies.
Dest: Allow this device as a destination for writing studies.
Name: Database
Volume Label: sparta
Device: Database
OK
Cancel

PG024643

The following table describes the features of the Configure Devices dialog:

Feature	Description
Select Device List Control	This list control provides information about each device. The Drive column displays the drive letter associated with the device. Some devices, such as the CD Writer, don't have a drive letter. The Format column displays the data format associated with the device. Typical formats are DICOM, Preload, Database and OEC. The Src column indicates whether or not the device is enabled as a source for the Open Study dialog box. A "-" indicates that the device can never be enabled as a source. Enabling a device as a source allows the device to appear in the Source list control on the Open Study dialog box provided there is data of that format on the device. The Dest column indicates whether or not the device is enabled as a destination for the Open Study dialog box. A "-" indicates that the device can never be enabled as a destination. Enabling a device as a destination allows the device to appear in the Destination list control on the Open Study dialog box. The Name column displays the name given to the device by the DICOMview® user. This is the name that appears on Source and Destination list controls on the Open Study dialog box. The Volume Label column displays the volume label of the device. Volume labels for removable devices and CD-ROMs are not shown because they vary

	depending on what media is inserted in the device. The Device column displays the type of physical device. Typical device types are CD-ROM, Removable, Local, Database, and Network.
Reset Device Preferences Button	Select this button if you wish to reset all the devices to their original default settings. All device settings will be restored to their original default values.
Edit Properties	This area displays the selected device's information. It also allows you to edit some of the device's properties. The Src check box allows you to enable or disable the device as a source device on the Open Study dialog box. The Dest check box allows you to enable or disable the device as a destination device on the Open Study dialog box. The Name edit box allows you to specify your own name for the device. This name will appear on the Open Study dialog box.

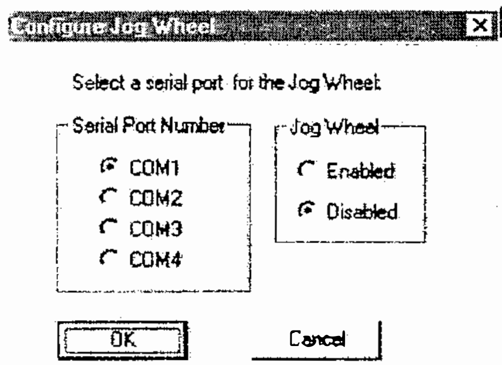
Use the left mouse button to select a device for editing. Only one device may be selected at a time. The selected device's information appears in the Edit Properties box that appears beneath the Reset Device Preferences button. You may edit the source, destination and name properties of a device within the Edit Properties box.

The device settings are kept in the registry and so are restored on each invocation of DICOMview®. Because of the way the settings must be stored in the registry, you may have difficulty with device settings if you mount non-disk devices on the network. or if you re-map local non-disk devices to different drive letters. If you have difficulty, resetting the devices to their default settings will allow you to re-map your local devices. You will have to reenter any settings that you wish to keep. Resetting the devices to their default settings will not help you if you have mounted non-disk devices on the network.

PG024645

4.10.2 Configure Jog Wheel

This dialog allows you to enable/disable the Jog Wheel and select the serial port for the optional jog wheel controller.



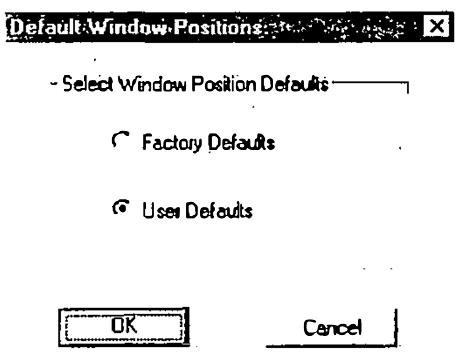
PG024646

4.11 Window Preferences

DICOMview® ships with a set of factory defaults controlling the position of the thumbnail images and the view window for playing cine images. You may institute your own set of defaults by dragging the thumbnail window and image-viewing window to the desired positions. Then select the View, Window Positions… menu item to bring up the Default Window Positions dialog.

Select User Defaults and press OK. Answer YES if you wish to use the current positions as your new default window positions. Answering NO will restore previous user defaults as the new window positions.

Or, select Factory Defaults and press OK to restore the factory settings as your window defaults.



Chapter 5

Optional Add-On Modules

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Your purchase of DICOMview® may have included one of the many add-on modules supported in DICOMview®. These add-on modules provide specific functionality fully integrated into the product. Some of the add-on modules available include:

- Analysis, which provides for manual LVA [left ventricular analysis], QCA [quantitative coronary analysis], and angulation measurements;
- CD Mastering, which allows for writing studies onto CD-R media;
- Pie Medical Analysis Integration, which adds functionality for exporting frames to Pie Medical's Analysis package; and
- Jog wheel controller for controlling cine playback.

If your initial purchase did not include any add-on modules, and you find later that you require the functionality of a specific module(s), you may add new modules at any time. Contact your sales representative for more information.

The next sections highlight each specific module in detail.

5.1 Analysis

The Analysis add-on module provides for fully integrated manual LVA [left ventricular analysis] and QCA [quantitative coronary analysis].

5.1.1 Left Ventricular Analysis (LVA)

LVA allows for the measurement of the left ventricle systolic and diastolic volumes. The area-length method is used for volume calculation. The left ventricular ejection fraction and stroke volume are calculated from the volume measurements. Perform LVA by following these steps:

- Open the patient study on which LVA will be performed.
- Open the image that contains the calibration marker.
- Calibrate the Analysis module to the calibration marker in the calibration image. Click on the calibration button on the Analysis toolbar to perform this task. A calibration dialog window will display, and a calibration line will appear in the open image window. Stretch the calibration line from one calibration mark to the next (most labs take one image which contains a calibration grid, or calibration ball). Enter in the calibration dialog window the length of the calibration line or choose a catheter French size and click OK.
- Once the image is calibrated, trace the diastolic and systolic left ventricular silhouettes.
- After each silhouette is traced, click on the automated axis placement button on the Analysis toolbar, and edit the major axis placement line if it is incorrect.
- Once all the traces and major axis lines have been placed, click on the calculate button on the Analysis toolbar to produce the volume measurements and ejection fraction. The measurements will be placed in the image window. You may click and drag the measurement boxes anywhere in the image window.
- You may print the image window or save the image window as a BIT map file for inclusion to the patient's medical record chart or your cardiac information management system.

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Notes on LVA tracing: the LVA module assumes that the user will trace the systolic and diastolic contours from the outside aortic root notch around the left ventricle to the opposite side of the aortic root notch. You do not need to close the trace, as the LVA module will automatically draw a straight line across the aortic root notch for you. If you do not trace the LV silhouette as described above, then the automated major axis determination will most likely be incorrect and you will have to manually correct its position. You can turn the displaying of a trace on or off by click the trace button in the Analysis toolbar on or off. This allow you to remove one trace from the image window while drawing the other trace.

Notes on LVA calibration: there is one and only one calibration that is persistent. When the calibration is set or reset it applies only to calculations going forward. Hence if you want to re-calculate with a new calibration, two actions must be performed, 1) you must recalibrate and 2) you must click on the calculate button. Any measurements onscreen will stay the same unless you click on the calculate button in the Analysis toolbar. The cross hair that indicates the length based on the calibration used for the displaying measurement will give a visual indication as to whether the measurements on screen were made with the current calibration setting. If your lab uses a persistent setting for all LV image shots, you may calibrate the Analysis module once, and it will use the same setting across DICOMview® sessions.

5.1.2 Quantitative Coronary Analysis (QCA)

QCA allows for the stenosis sizing of lesions in the coronary artery tree. The percentage of stenosis is reported by the QCA package. To use this package you must manually trace the length of the closed portion of the arterial lesion and then manually trace the length of an open portion of the artery above the lesion. To perform these steps use the following procedure:

- Open the patient study on which QCA will be performed.
- Open the image that contains the calibration marker.
- Calibrate the Analysis module to the calibration marker in the calibration image. Perform this task by clicking on the calibration button on the Analysis toolbar. A calibration dialog window will display, and a calibration line will appear in the open image window. Stretch the calibration line from one calibration mark to the next (most labs take one image that contains a calibration grid, calibration ball. or banded catheters). Enter in the calibration dialog window the length of the calibration line or choose a catheter French size and click OK.
- Once the image is calibrated, click on the QCA button in the Analysis toolbar to turn on stenosis sizing.
- In your image window, measure the diameter of the artery you are interested in sizing. Do this by clicking and dragging the mouse from one edge of the artery to the other.
- Perform the last step a second time, but measure the diameter of the artery where the lesion occurs. Do this by clicking and dragging the mouse from one edge of the lesion artery to the other.
- Edit the lines if needed: do this by dragging the end of the line you wish to edit.
- Once both lines have been traced, text will appear displaying the percentage of stenosis of the lesion.
- You may click and drag the text to other areas around the two traces if you wish.

- Repeat the above procedure for other lesions you are interested in for this patient study.

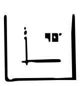
Notes on QCA calibration: there is one and only one calibration that is persistent. When the calibration is set or reset it applies only to calculations going forward. Hence if you want to re-calculate with a new calibration, two actions must be performed, 1) you must recalibrate and 2) you must click on the calculate button. Any measurements onscreen will stay the same unless you click on the calculate button in the Analysis toolbar. The cross hair that indicates the length based on the calibration used for the displaying measurement will give a visual indication as to whether the measurements on screen were made with the current calibration setting.

5.1.3 Electronic Calipers

Electronic Calipers allow for the measurement of any length in an image window. To use the Electronic Calipers you must first calibrate your image and then click on the Electronic Calipers button. Once the Electronic Calipers button is depressed you may measure any length in your image window by clicking and dragging the mouse across the object in the image you wish to measure. You may select any Electronic Caliper trace and edit it by clicking and dragging the ends of the line. You may also selectively erase any Electronic Caliper trace on your image widow by selecting it and clicking the erase button in the Analysis toolbar.

5.1.4 Angulation Measurement

Customers purchasing the Analysis module can perform angle measurements on the paused image. After selecting the Angle icon,



use the mouse to draw two intersecting lines on the screen. Once the lines intersect, the angle measurements will be presented. You may then print or export the image with the angle measurements included.

5.2 CD Mastering

The CD Mastering module allows for the storing or copying of images to CD-R media. This module allows you to make copies of your patient studies, or to remove patient demographic information from the study for displaying the study at a conference where you wish to protect the patient's confidentiality.

If the studies you select for write do not fit on a single CD-ROM, DICOMview® will allow you to remove the full CD-ROM, insert a new blank CD-ROM and continue the write. This allows you to split a study between multiple CD-ROMs if necessary. This allows you to archive studies which contain more images than can fit on a single CD-ROM.

To use the CD Mastering module perform the following steps:

- Have the study you wish to copy in the CD-ROM drive, OEC Jaz drive, or preloaded to the system you are on. Make sure you are at a system with a CD writer. Insert a blank piece of CD-R media into the CDR writer.
- To write a CD-R, click on the **Copy Study** toolbar button. This will open a dialog window allowing you to choose study(s) to be copied.
- In the *Copy Study* dialog window, choose the source with the study or studies you wish to copy to the CD-R. Studies may be from a CD-ROM, OEC Jaz drive, or preloaded on your local hard disk, or network drive.
- Once you have chosen the source, click on the Show button to display all of the studies from the chosen source. You may also search the source by filling out the search criteria portion of the dialog window. Please see the above section *Working with DICOM media* for directions on using the searching capabilities in DICOMview®.
- The studies from the source you specified above will be displayed in the bottom box in the *Write Study to CD* dialog window. Select the studies you wish to copy to CD-R by clicking on them. You may select multiple studies by holding down the CTRL key on your keyboard while clicking on the studies you wish to select.
- After your have selected the studies you desire to copy to CD-R, click on the **Copy or Copy with Edit** button.
- If "Copying with Edit", select images for copying and modify demographics if necessary as described in Section TBD.
- The study will be written to your CD-R media. This process may take several minutes.

Notes on CD Mastering: In order to write a CD DICOMview® must have a staging area on a local hard disk to prepare the image files for writing to the CD-R media. This would typically be your c: drive. This means that your c: drive must have enough free space on it to write the image files to the staging area on you c: drive. If you plan on having one station as you primary CD Mastering station, you should plan to have enough free space to stage studies. If you have an additional drive in your system (e.g. d: or e:) you may specify that drive for CD staging via the File, Preferences menu choice.

The CD-R media can hold no more than 650 MB of image data. Therefore if you always keep 650 MB free on your staging hard disk you will never get a message warning you that the CD Mastering could not take place because DICOMview® did not have enough free staging hard disk space. If you typically produce studies that are less than 650 MB, you make decrease the staging free space needed on your local hard drive.

Notes on CD-R Media: The CD-R media can hold no more than 650 MB of image data. Depending on the typical size of studies produced at your location, you must keep in mind how many studies you will typically be able to fit on one CD-R media. Generally, you will be able to fit four to seven patient studies on one CD-R media. DICOMview® will warn you if you have selected too many studies to fit on one CD-R media.

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5.2.1 Self-Playing CDs

In addition to writing the DICOM information onto the CD-R media, DICOMview® also writes a program which will enable the CD to play itself back on any Windows 95/NT PC. You can therefore distribute the media and be sure any recipient with a Windows 95/NT PC will be able to view the images.

5.3 Pie Medical Analysis Integration

The Pie Medical Analysis module allows for the exporting of frames within DICOMview® to Pie Medical's Windows-based Analysis software. To configure DICOMview® for use with your Pie Medical software perform the following procedures:

- Open the Pie Medical Frame Selection window within DICOMview® by selecting *Open Frame Selection Dialog...* from the **Pie Medical** menu.
- Click on the *Settings...* button in the Pie Frame Selection window.
- In the Settings dialog window, you must type the path where your Pie Medical QCA executable, LVA executable, and your image files directory are on your hard disk. (*Note:* your image files path must be the same one your Pie Medical software is set-up to look in.)
- Once you have entered the appropriate path settings, click the OK button.
- You are now ready to use your Pie Medical Analysis module.

The Pie Medical Frame Selection window allows you to select up to five frames (or image snapshots) for export into your Pie Medical Analysis application. Use the Pie Medical module by selecting frames from image windows in DICOMview®. When you have added all the frames you wish to export into your Pie Medical Analysis application, click on the *Launch QCA...* or *Launch LVA...* button. This will start up your Pie Medical application and your selected frames will automatically be imported and ready for measuring. To end your Pie Medical Analysis module session within DICOMview® click on the *Close* button in the Pie Medical Frame Selection window.

5.4 OEC Media Integration

The OEC Media Integration module allows you to display and write images from OEC media (typically this is a Jaz drive) from within DICOMview®. If you have purchased this module your version of DICOMview® will have OEC Jaz drives as a source media in the open study dialog window.

5.5 Heartlab Hand Controller

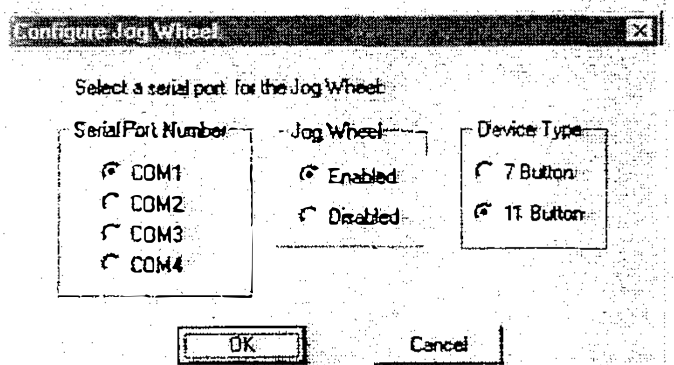
Overview

The MCS3 hand controller is a serial port device that allows you to perform a limited number of operations for the image view such as play, pause, previous and next.

Selecting the Hand Controller Device

MCS3 hand controllers will be shipped with DICOMview™ versions 1.9 and later. However, versions 1.9 and later will provide support for the MCS2 controller.

Device selection, i.e., MCS2 or MCS3, will be provided by a set of two radio buttons on the Configure Jog Wheel dialog. The radio button options will be identified as the "7 Button" device (MCS2) and the "11 Button" device (MCS3). The default device will be the 11 Button device. MCS2 users will have to select the 7 Button option prior to using their hand controllers.



- Play/Pause - Pressing the Play/Pause button will toggle the playing of the image loop.
- Loop - Pressing the Loop- button will change the image to the previous image in the study. It operates only in a stepwise fashion.
- Loop+ - Pressing the Loop+ button will change the image to the next image in the study.
- Frame- - Pressing the Frame- button will change the frame to the previous frame in the image loop.
- Frame+ - Pressing the Frame+ button will change the frame to the next frame in the image loop.
- Pan Stick - The pan stick has four positions: up, down, left and right. Pressing the stick up will cause an image to pan so that the upper portion of the image becomes visible. Pressing the stick to the left will cause an image to pan so that the left portion of the image becomes visible. Similar actions should happen for the down and right positions.
- Brightness- - Pressing the Brightness- button will decrease the brightness.

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- Brightness+ - Pressing the Brightness+ button will increase the brightness.
- Contrast- - Pressing the Contrast- button will decrease the contrast.
- Contrast+ - Pressing the Contrast+ button will increase the contrast.
- Zoom- - Pressing the Zoom- button will cause the image to zoom out.
- Zoom+ - Pressing the Zoom+ button will cause the image to zoom in.
- Jog Wheel - If the image loop is paused, turning the jog wheel clockwise will cause the frame number to increase. If the frame number is already the last frame in the image loop, the frame number will advance to the first frame in the image loop.

  If the image loop is paused, turning the jog wheel counter-clockwise will cause the frame number to decrease. If the frame number is already the first frame in the image loop, the frame number will advance to the last frame in the image loop.

  If the image loop is playing at a speed other than 0 fps. turning the jog wheel will do nothing. If the image loop is playing and the speed is 0 fps, turning the jog wheel will first pause the image and then the jog wheel perform its usual action.
- Speed Shuttle - The speed shuttle allows you to select the speed of play. The middle position on the shuttle corresponds to 0 fps. The rightmost position corresponds to +4x. The leftmost position corresponds to –4x.

  If the image loop is playing, the shuttle's speed setting is applied immediately. If the image loop is paused, turning the shuttle will cause the image loop to start playing and then the shuttle's speed setting is applied.

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Chapter 6

Troubleshooting

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6.1 Troubleshooting

Heartlab works closely with medical systems vendors to assure compatibility with the DICOM interchange media produced by their cath labs. It is possible that you may encounter Media which does not fully comply with the DICOM interchange standard. Should this event arise contact your sales person or support center for assistance.

You may also wish to consult our Quick Start Guide, which contains several tips for solving common problems.

pacsgear

User's Manual

MediaWriter 4.0 CD/DVD Burning Solution

PACSGEAR™

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EXHIBIT 217
Deponent Rowberg
Date 12/16/11 Rptr. SP
WWW.DEPOBOOK.COM

Exhibit 217

MediaWriter

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Use of Ficticious Patient Data

Patient demographics appearing in this manual are examples only. No actual patient study data were used in the preparation of this manual. Any similarities to persons living or deceased is purely coincidental.

Indications for Use

MediaWriter is intended to be used by authorized staff to create DICOM CDs/DVDs/USB flash drives. These media can contain imaging studies, reports and related patient information. Operations used to create the media include patient selection, study confirmation, label customization, and DICOM configuration.

CE

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pacsgear

Contents

pacsgear

1 Welcome

MediaWriter

Congratulations on adding MediaWriter™ to your PACS/EHR system.

MediaWriter writes DICOM studies, results, and an optional viewer to CDs, DVDs, and USB flash drives. The MediaWriter System includes a CD/DVD burner with a built-in media label printer that prints color labels directly to disc. MediaWriter includes additional features to scan documents, create electronic forms, and import multimedia files.

New Features for MediaWriter 4.0

- **GEARView™ Basic**, a DICOM study and report viewer from PACSGEAR, is now included during installation. The installation program does not change the default viewer configuration, but adds **GEARView Basic** as a viewing option. For new installations, **GEARView Basic** is installed as the standard viewer.
- A new advanced labeling option provides greater control over backgrounds and text placement. Sample background templates are included, and custom backgrounds are available for a small fee. Contact PACSGEAR Sales for details.
- MediaWriter 4.0 supports Windows 7 for all CD/DVD burners except Rimage. Customers with Rimage publishing solutions should continue to use MediaWriter 3.0.4.
- For increased ease-of-use, the audit log can now be exported as a text (.csv) file.
- Reduce the number of images auto-burned to CD/DVD with image-level filtering by DICOM tag. Contact PACSGEAR Support for details.
- For enhanced security, the **MediaWriter** Report Server can now store encrypted reports. Contact PACSGEAR Support for details.
- Adobe® PDF files can be auto-burned to CD/DVD when placed in a selected folder. Contact PACSGEAR Support for details.

For more information, please contact us:

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PG-DOC-MW-UM-EN-REV4.0A

Glossary of Terms and Symbols

The following terms and symbols are used in PACSGEAR manuals.

[i]	*Consult instructions for use.* Appears on the product CD.
CE	*Conformité Européenne*: Indicates that the product complies with the requirements of the 93/42/EEC Medical Device Directive.
	Symbol for *manufacturer.*
EC REP	Symbol for *European authorized representative.*
Accession number	A tracking or order number for patient studies.
AE	*Application entity.* A local or remote DICOM service.
AMD	*Automatic marker detection.* Automatic detection of markers to identify mammography image orientation.
AST	*Auto segmentation technology.* Pacsgear's proprietary technology for converting sectional films into a stack or cine loop.
Burner	A digital recording device such as a CD recorder that stores data on media.
DICOM	*Digital imaging and communications in medicine.* A networking standard for the medical industry.
DOB	*Date of birth.*
DCA	*Dynamic contrast algorithm.* Pacsgear's proprietary technology for displaying mammography film priors with a digital "look and feel."
DX	DICOM modality abbreviation for *digital mammography.*
EMR	*Electronic medical records.*
EHR	*Electronic health records.*
LDAP	*Lightweight directory access protocol.* Used for looking up network services and addresses.
Media	Electronic storage media, such as CD-ROM and DVD.
Modality	Sources of data, such as from ultrasonography, MRI, PET, and CT.
MRN	*Medical record number.* Sometimes referred to as the "patient ID number."
PACS	*Picture archival and communication system.*
PacsSCAN	General term for any of the **PacsSCAN** products (**PacsSCAN** Film, **PacsSCAN Video**, etc.)
CAUTION	Indicates information necessary to prevent damage or loss of data or equipment.

pacsgear

Operating Procedure Conventions

Operating procedures employ the following conventions.

Convention	Indicates
Boldface type	Names of buttons.
Italic type	Names of on-screen objects other than buttons (such as menu commands).
`Courier font`	Text that the user types.
>	Sequence of procedures.

Starting and Exiting MediaWriter

Start and exit MediaWriter as you would any Windows program. When starting, a splash screen appears with the product name. If the splash screen does not appear, please contact PACSGEAR Support.

Licensing MediaWriter

To start using MediaWriter, you must obtain and enter a license key as follows.

1 Start MediaWriter. If a license key has not been previously entered (such as the first time you run the program), the license key entry dialog box (see figure below) appears. Write down the value that appears in the System ID box. To display the dialog box manually at any time you can click *Help* > *About* > *Change*.

2 Request a license key by contacting PACSGEAR support via e-mail at key@pacsgear.com, telephone at +1 925 226 6100, or the support section of our Web site at www.pacsgear.com. Provide the following information to PACSGEAR:

Hospital Name, City, State, Country, Product Name, System ID, and Department/Workstation.

If your license is for Demo mode only, select the *Click to activate demo* check box.

3 Enter your license key and expiration date and click **OK**.

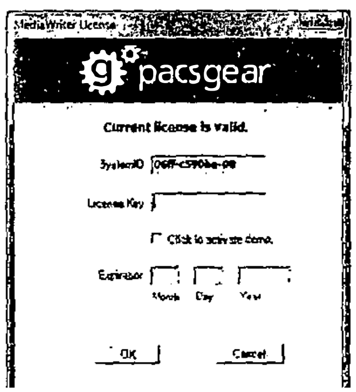

Figure 1.1 License key entry dialog box

Logging On for the First Time

After you have licensed the product, you will be prompted to log on the first time you start the program. The default logon is admin, with no password. Unless multiple users have been configured (see chapter "8 Managing Users"), you will not be required to log on thereafter.

When logged on as "admin" (administrator), the Settings menu becomes available for configuring MediaWriter. Note that the menu commands may differ from those that appear in this manual depending on the type of license purchased.

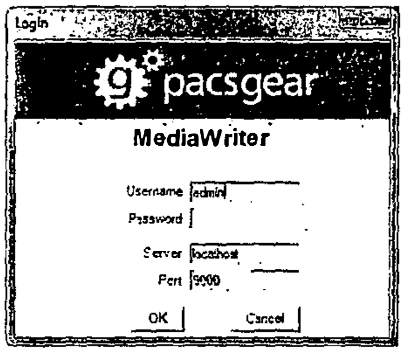

Figure 1.2 Logon dialog box

2 Settings

2.1 Entering DICOM Settings

Before burning studies to media, you must enter DICOM settings and burner settings (see section "2.2 Entering Burner Settings"). DICOM settings identify MediaWriter to your PACS and specify archives from which to acquire studies for burning.

Entering DICOM Settings

1 Click *Settings > DICOM*.

The DICOM Configuration dialog box appears.

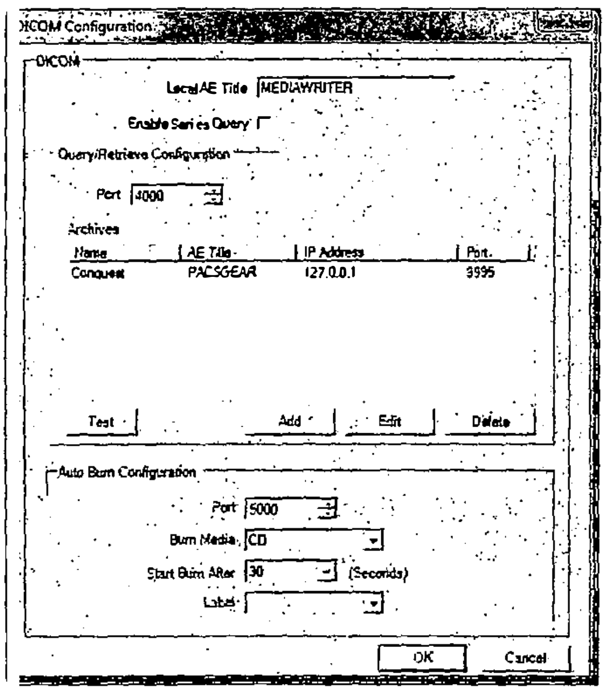

Figure 2.1 DICOM settings dialog box

2 Enter the settings described below as needed, and then click **OK**.

Local AE Title

Enter a title used to identify MediaWriter to your PACS. The default AE title is MEDIAWRITER.

Enable Series Query

When you query an archive for studies to burn, MediaWriter displays the results in the main screen (see Chapter 3). By default, MediaWriter displays query results as complete studies, one on each line. However, if you select the Enable Series Query check box, a plus sign (+) appears next to studies that contain series. You can click the plus sign to view the contents of a series, and then select individual items for burning.

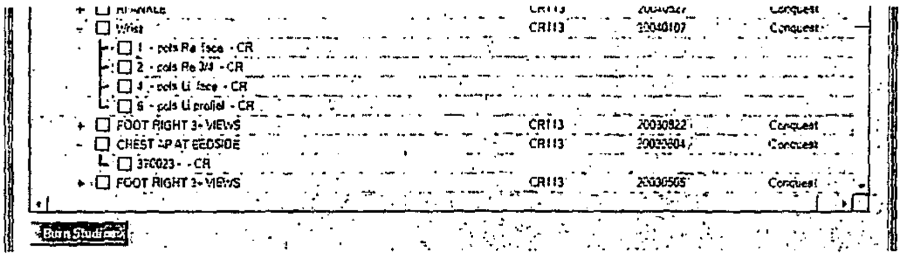

Figure 2.2 Query results when series querying is enabled

Query/Retrieve Configuration

Port

In the Port box in the Query/Retrieve Configuration area, type or select the number of the port that MediaWriter should use to query and retrieve DICOM studies.

Adding a New Archive

To query and retrieve studies from an archive or device, you must first enter DICOM settings for the archive. MediaWriter sends queries to these archives in order to retrieve studies to be burned. In the Archives table of the DICOM Configuration dialog box:

1 Click **Add**.

The Add/Edit Archive dialog box appears (see figure 2.3 below).

2 Enter the relevant information for the archive that contains the studies you wish to burn, then click **OK**. Consult with your PACS administrator for the correct settings for your PACS.

Editing an Existing Archive

To edit an existing archive:.

1 Select an archive.

2 Click **Edit**, edit the relevant settings, then click **OK**.

Deleting an Archive

To delete an archive, select the archive and click **Delete**.

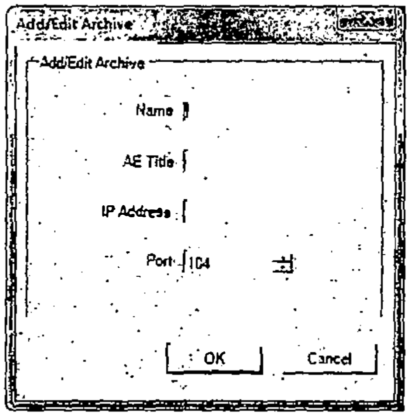

Figure 2.3 Add/Edit Archive dialog box

Testing a Connection to an Archive

You can test whether **MediaWriter** is able to connect with and query an added archive. In the Archives table of the DICOM Configuration dialog box:

1 Select an archive.

2 Click **Test**.

The Test Results dialog box appears, indicating whether the test passed or failed.

3 Click **OK**.

If the test failed, check to make sure you entered the correct settings, or consult with your PACS administrator.

Auto Burn Configuration

You can configure **MediaWriter** to burn studies automatically as soon as they are sent by modalities.

Port
Type or select the DICOM port number. Only studies sent to the specified port will be burned automatically.

Burn Media
Select the type of media onto which studies will be burned.

Start Burn After
Select the number of seconds before burning starts. When transmission of a study from an archive stops, **MediaWriter** waits this number of seconds before starting the auto burn.

Label
Select a label to burn onto the media.

- The label selected here is only used for auto burn. For other jobs, you can select a label at burn time in the Burn Confirmation dialog box.
- The Label list in the DICOM settings dialog box is blank unless you publish at least one label in the Disc Label Configuration dialog box.

2.2 Entering Burner Settings

Before burning studies to media, you must enter DICOM settings (see section 2.1, "Entering DICOM Settings") and burner settings. Burner settings allow you to select a burner device (such as your PC's CD-ROM drive), ports, media types, and other parameters.

1 Click *Settings > Burner.*

The Burner Configuration dialog box appears.

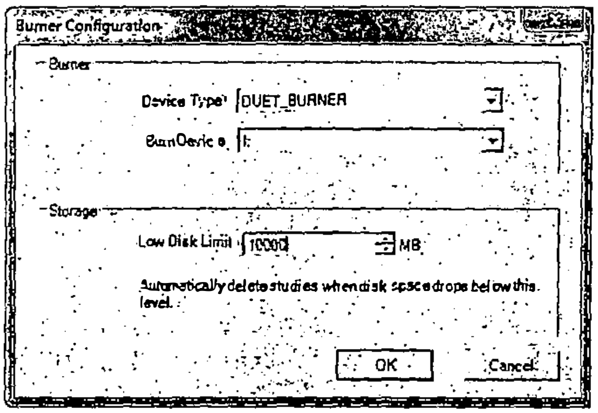

Figure 2.4 Burner Configuration dialog box

2 Enter the settings described below as needed, then click **OK**.

Device Type
In the *Device Type* list, select the type (brand) of device to be used to burn studies. The available devices are those previously installed on the PC that is running **MediaWriter**.

Burn Device
In the *Burn Device* list, select the drive/name of the device used to burn studies.

Low Disk Limit
The low disk limit is the minimum amount of free space on the server's hard drive. When this limit is reached, **MediaWriter** automatically deletes old studies to make room for new studies. In the *Low Disk Limit* box, type or select the desired number of megabytes. The default is 10000 MB.

2.3 Entering Encryption Settings

MediaWriter can protect patient confidentiality by encrypting studies. Once studies are encrypted, they can only be viewed by entering a password.

1 Click *Settings > Encryption.*

The Encryption Configuration dialog box appears.

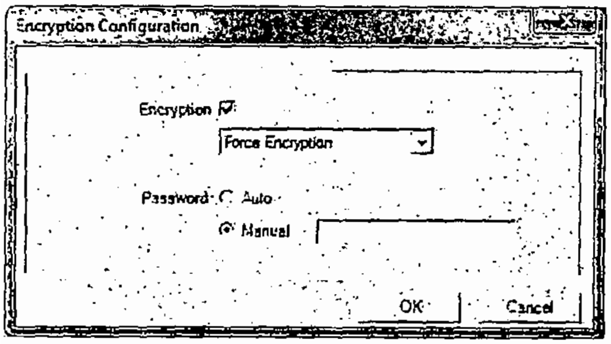

Figure 2.5 Encryption Configuration dialog box

2 Enter the settings described below as needed, then click **OK**.

Encryption

Check box
Select/clear to turn encryption ON/OFF.

List
Select one of the following to specify how encryption is applied.

Force Encryption
Encryption is always ON, and cannot be turned OFF by the user.

Selected By Default
Encryption turned ON by default, and can be turned OFF by the user.

Cleared By Default
Encryption is turned OFF by default, and can be turned ON by the user.

Password

Choose one of the methods below to enter the password required for viewing studies. Passwords are case sensitive, and any character can be used.

Auto
Select to have MediaWriter automatically enter a password in the box.

Manual
Select, then enter your own password in the box.

3 Searching for, Selecting, and Burning Studies

Once you have entered DICOM and burner settings, you are ready to search for studies and burn them to media.

3.1 Searching for and Selecting Studies

Searching for Studies

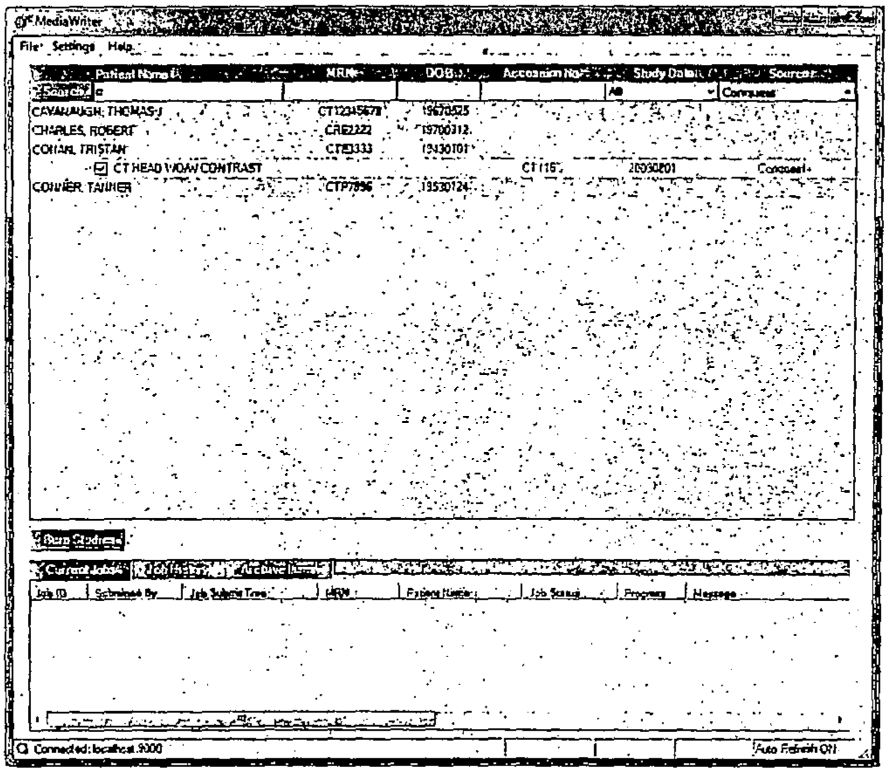

Figure 3.1 Patient study search results

From the main screen, search for patient studies by typing or selecting search criteria in the *Patient Name, MRN, DOB, Accession No., Study Date,* and *Source* boxes and clicking the **Search** button. For example:

In the Patient Name box, type C, then click **Search.**

MediaWriter searches the archive you specified under *Source* for studies that match your criteria (in this example, patients whose last names begin with "C"). Patients matching the search criteria appear in the gray rows.

pacsgear

Notes on Search Syntax

You can use the "star" (*) wildcard in the Patient Name, MRN, DOB, and Accession No. fields. For example, typing 9* in the MRN field finds all studies whose MRN numbers begin with 9. Typing *4 finds all that end in 4. Also, while you do not need a star in the Patient Name field (the software assumes that the characters entered are the first characters of the patient's last name), you *must* use a star in the MRN, DOB, and Accession No. fields, or else *enter the exact number* you wish to search for.

Selecting Studies

1 Click anywhere on a gray row to display all of the studies (appearing in the white rows) for the patient. By default, all studies for the patient are selected.

2 Select or clear the check boxes of the studies that you wish to burn using the following procedures.

Action	Procedure
Select a single study	Select the corresponding check box
Unselect a single study	Clear the corresponding check box
Select all studies for a single patient	Right-click any patient study and click *Select All* in the shortcut menu
Unselect all studies for a single patient	Right-click any study and click *Unselect All* in the shortcut menu

Note: When you click a new gray patient row, any previously displayed white study rows become hidden, and will not be selected for burning.

3.2 Burning Selected Studies to a Medium (Single Patient)

1 Click **Burn Studies**.

Burn Studies button

The burn confirmation dialog box appears.

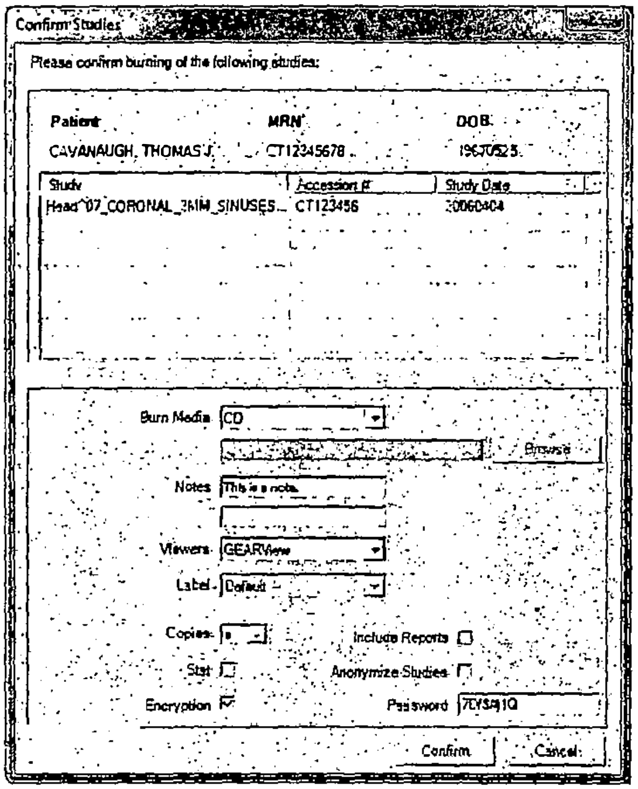

Figure 3.2 Burn confirmation dialog box

2 Enter the settings below as needed, then click **Confirm**.

MediaWriter begins burning the selected studies to the media, and adds a job to the Current Jobs tab (below) in the bottom part of the main screen.

Burn Media
Select the type of media on which to burn the studies. MediaWriter supports the following media types: CD (standard CD-ROMs), DVD SINGLE (single-sided DVDs), DVD DUAL (dual-sided DVDs), and USB MEDIA (such as USB memory sticks).

Browse
When USB MEDIA is selected under Bum Media, the box to the left of this button contains the path to the USB media device. If necessary, click **Browse** to change the path.

Notes
Enter descriptions or other information to physically print on the media for the current burning job. You can enter up to sixteen characters in the first box, and up to fifteen characters in the second box. Note that these "Notes" differ from the "Custom Labels" in the Disc Label Configuration dialog box, which apply to all burning jobs. The notes boxes are dimmed if the Advanced Label option is selected in the Disc Label dialog box.

Viewers
Select the viewer that will display the studies. PACSGEAR's **GEARView Basic** is a viewer program that allows physicians and patients to open DICOM studies on standard PCs without the need for high-end PACS hardware or software. If needed, you can bum the **GEARView Basic** viewer onto the media at the same time as the studies. MediaWriter also supports a variety of other viewers. Please contact your sales representative for more details.

Label
Select the label to be printed onto the media. The list only contains labels that are selected as *Published* in the Disc Label Configuration dialog box, and is dimmed if the Simple Label option in that dialog box is selected.

Copies
Select the number of copies to bum. Each copy is burned separately.

Include Reports
This check box is only available when the Enable Reports check box is selected in the Reports configuration dialog box. When selected, MediaWriter adds reports to the burn job.

Stat
Select this check box to have MediaWriter perform the burn job immediately (before any others that may be listed in the Current Jobs tab).

Anonymize Studies
Select to omit the following information from the studies: patient name, MRN, referring physician, physician of record, performing physician, reading physician, operator, birth time, and institution.

Encryption
Select the check box to encrypt the studies on the medium. This check box is only available if the Enable Encryption check box is selected in the Encryption Configuration dialog box. If Force Encryption was selected in that dialog box, the Encryption check box is selected and dimmed.

Password
Enter a password to be required for viewing studies. This box is only available if the Enable Encryption check box is selected in the Encryption Configuration dialog box. If Auto was selected in that dialog box, the Password box is filled automatically with a random password.

Note

Be sure to write down the password before burning studies.

Current Jobs Tab

The Current Jobs tab shows the progress of burning of the studies selected from the search results.

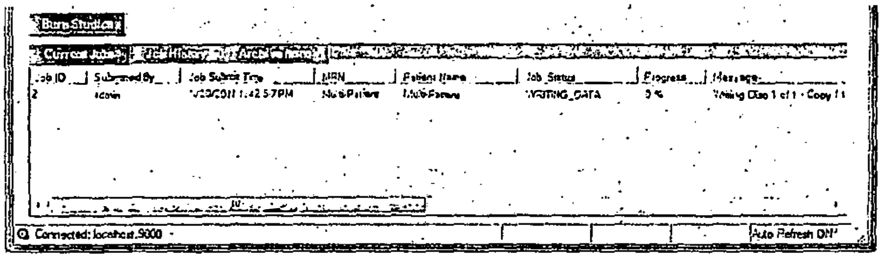

Figure 3.3 Current Jobs tab of the main screen

The Current Jobs tab displays a unique job ID for each job, followed by specific information such as the user who started the job (Submitted By), the time the job was started (Job Submit Time), MRN, patient name, job status, progress (of the burn job), and messages. If a job cannot be completed, the row containing the job appears in red and an error message is displayed.

Refreshing Job Information

The job status, progress, and messages change as burning progresses. However, changed information will not appear in the Current Jobs tab unless refreshed. Job information can be refreshed automatically or manually as described below. For details on Auto Refresh settings, see section 9.3, "Auto Refresh."

Turning Auto Refresh On and Off

Right-click anywhere in the Current Jobs tab, then click *Auto Refresh Off* or *Auto Refresh On* (whichever is displayed) in the shortcut menu.

Refreshing Manually

If Auto Refresh is OFF, you can right-click anywhere in the Current Jobs tab, then click *Refresh* in the shortcut menu to refresh the job information manually.

Cancelling a Job

Right-click on the job you wish to cancel, then click *Cancel Job* in the shortcut menu. The job is canceled and removed from the Current Jobs tab.

Retrying a Job

If a job experienced an error but the error was corrected, you can retry the job. This saves you from having to create the job over again. Right-click on the job you wish to retry, then click *Retry Job* in the shortcut menu.

Spanning Discs

If you burn a study that cannot fit onto a single disc, or if you choose to burn more than one copy of the study in the Burn Studies confirmation dialog box, MediaWriter will prompt you to insert a new disc when the current disc becomes full. Note that this only applies when using a single-disc burner.

3.3 Burning Selected Studies to a Medium (Multiple Patients)

The procedure for burning studies from multiple patients is slightly different than that for single patients.

1 In the main window, click the *Archive Items* tab.

2 Search for studies you wish to burn by following the procedure in section 3.1.

3 Select a study and click **Add Item**.

The study appears in the Archive Items tab. Repeat this procedure for all other studies you wish to burn. If you need to remove a study from the list before burning, right-click the study and select *Remove Patient* on the shortcut menu.

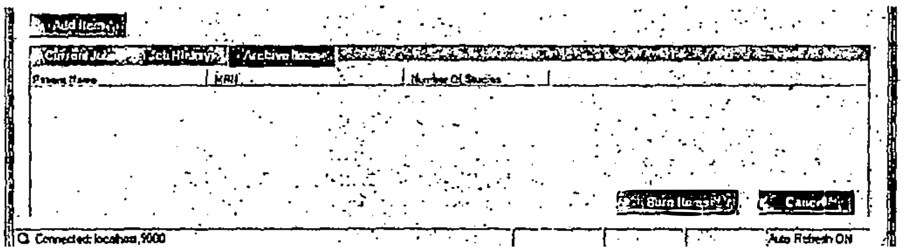

Figure 3.4 Archive Items tab

4 Click **Burn Items**.

The burn confirmation dialog box for multiple patients appears. Note that this is identical to the burn confirmation dialog box in figure 3.2, except that the patient study list is omitted.

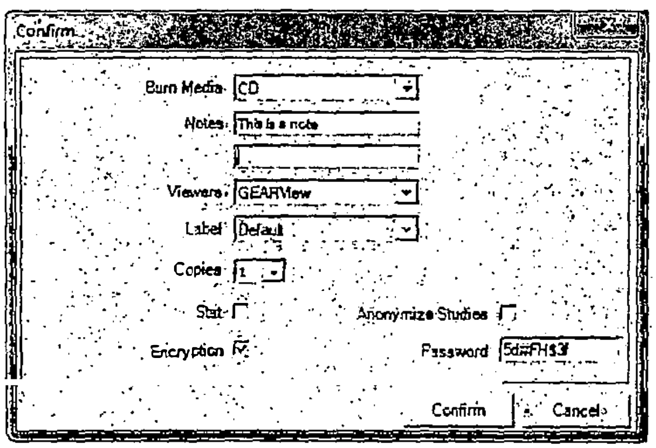

Figure 3.5 Burn confirmation dialog box for multiple patients

5 Enter settings as needed, then click **Confirm**. A new job is added to the Current Jobs tab, and burning begins.

Job History Tab

Each time a burn job is successfully completed, a record of the job is added to the Job history tab. Jobs remain in this tab for twenty-four hours, after which time they are removed automatically. To view the job history, click the **Job History** tab.

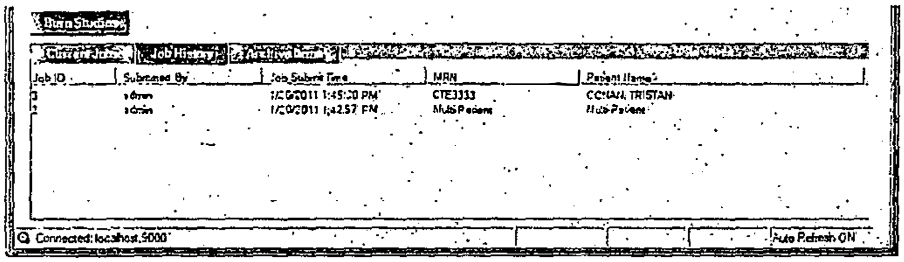

Figure 3.6 Job History tab

Resubmitting Jobs

You can resubmit any job that appears in the Job History tab by right-clicking the study and clicking *Resubmit Job* on the shortcut menu.

Refresh

To refresh the contents of the Job History tab, click *Refresh* on the shortcut menu in the step above.

4 Printing Labels on Media

4.1 Simple Labels

Printing labels requires a CD/DVD burner with a built-in printer. The burner/printer allows you not only to store DICOM studies on an external media such as a CD, but also to print text and images (a "label") directly onto that medium at the same time. There are two kinds of labels, *Simple* and *Advanced*. Simple labels can consist of a logo or other image plus seven lines of text of up to fifty characters each. To create a simple label, perform the procedure below. For information on advanced labels, see section 4.2 Advanced Labels.

1 Click *Settings > Disc Label*.

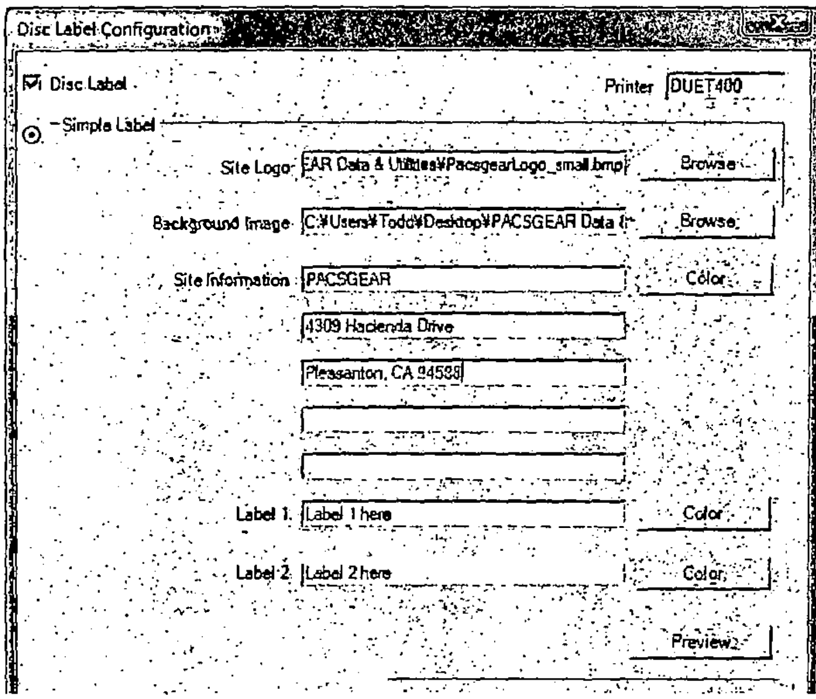

Figure 4.1 The Simple Label group of the Disc Label Configuration dialog box

2 Type or select settings as needed according to the descriptions below, and then click **OK**.

Disc Label
Select the **Disc Label** check box to turn ON printing of labels.

Printer
Displays the name of the printer selected in the Burner Configuration dialog box.

Simple Label
Select to print a simple label. Select *Advanced* to print an advanced label.

Site Logo
In the *Site Logo* box, type the path and file name to the desired image file (typically, the logo of the medical institution). Or, click **Browse**, then navigate to the image file, select it, and click **Open**. When printing the label, **MediaWriter** will size the image automatically and place it in the top center of the medium.

Background Image
In the *Background Image* box, type the path and file name to the desired image file, or click **Browse**, then navigate to the image file, select it, and click **Open**. When printing the background image, **MediaWriter** will size the image automatically to so that the width and height of the image match—as closely as possible—the diameter of the disc medium (see the example under "Preview" below).

Site Information
Under *Site Information*, type up to fifty characters in each box. This text will appear in the top center of the media, just below the site logo.

Label 1 and Label 2
Labels 1 and 2 are printed on the left side of the medium every time a medium is printed. Note that these labels differ from the Notes in the Burn confirmation dialog box, which only appear on a per-job basis.

In the *Label 1* and *Label 2* boxes, type up to fifteen characters each.

Color Buttons

You can specify a text color for the site information and custom labels.

1. Click the **Color** button corresponding to the text whose color you wish to change. A standard Windows color selection dialog box appears.
2. Click the desired color, then click **OK**. The text appears in the selected color, both in the dialog box and in the print preview screen.

Preview

In the *Simple Label* group, click **Preview**. A window appears containing a preview of the disc label that you configured. This label will be printed on the media whenever you burn studies.

Note that some information other than that entered by the user is also printed on the media including the patient name, DOB, MRN, study creation date and time, the station ID, Disc ID, exam dates, types, and body parts.

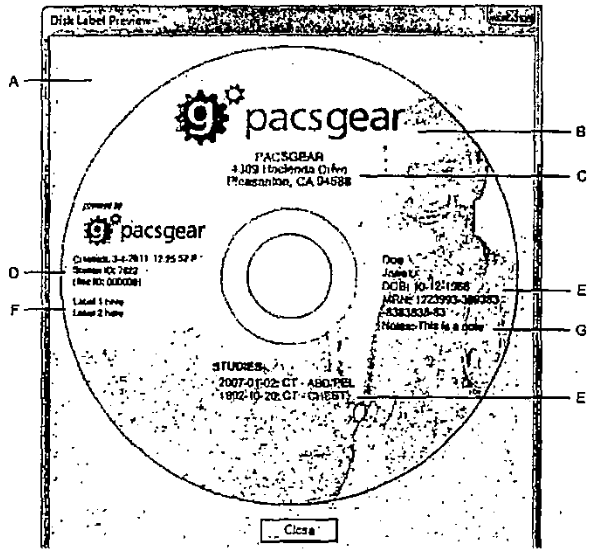

Figure 4.2 Print Preview screen

- **A** Background image
- **B** Site logo
- **C** Site information
- **D** Printed automatically (not editable by the user)
- **E** Preview window displays examples (only) of various study information
- **F** Custom labels (from Disc Label Confirmation dialog box)
- **G** Notes (from the Burn confirmation dialog box)

4.2 Advanced Labels

In contrast to simple labels, advanced labels offer the user more freedom and detail in design. To create an advanced label, perform the procedure below.

Procedure

1 Click *Settings > Disc Label.*

The Disc Label Configuration dialog box appears.

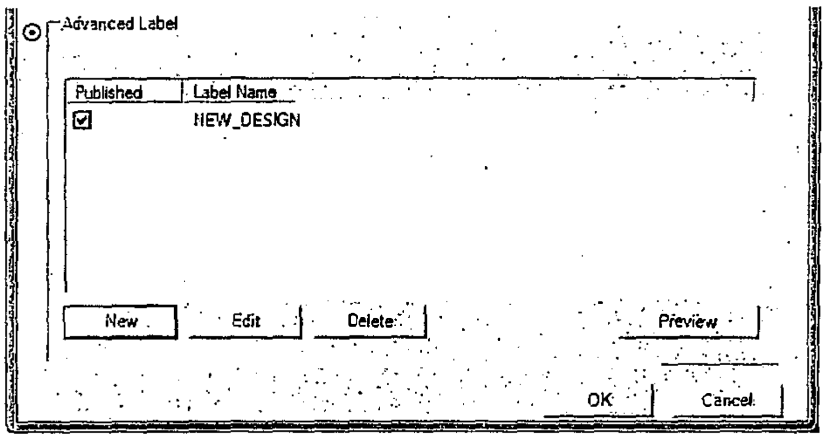

Figure 4.3 Advanced Label group of the Disc Label Configuration dialog box

2 Select the *Advanced Label* option.

3 Click **New** to display the Select Template dialog box. Select a template and click **OK**.

Alternatately, you can select an existing label in the *Label Name* list above and click **Edit**.

4 Follow the instructions below under "Label Designer."

Publishing an Advanced Label

Publishing an advanced label means to make it available in the *Label* lists of the DICOM settings dialog box, and the Burn Confirmation dialog boxes for single and multiple patients. To publish one or more labels, select the corresponding check boxes as shown in the figure above.

Print Preview

Select a label and click **Preview**. The preview is similar to the one for simple labels, but its contents consist only of items you specified in the Label Designer.

Label Designer

The label designer contains powerful tools for creating advanced (customized) labels. Use the tools described below to create your label, then save your design and close the designer using the **Exit** tool bar button.

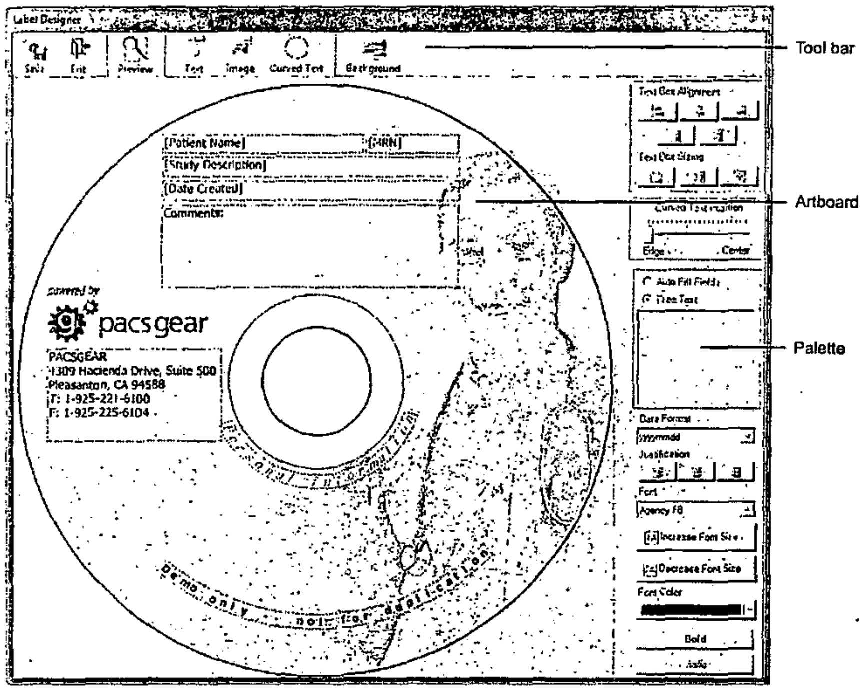

Figure 4.4 Label Designer

Tool Bar

Use the tool bar to add new items to the label, and to preview and save your work. The tool bar contains the following tools.

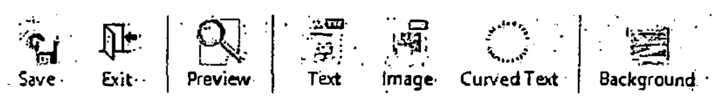

Figure 4.5 Tool bar on the Label Designer

Save
Click to name and save your label. The name will appear in the Disc Label Configuration dialog box the next time it is opened.

Exit
Click to close the label designer and return to the disc label configuration dialog box.

Preview
Click to display a preview of your label.

Text
Click to place a text box on the artboard. After placement, you can type desired text into the box, or move or resize the box using the mouse. For additional text editing options, see "Palette" below.

Image
Click to open the New Image screen for selecting an image to place on the artboard. The first time you click this tool, the New Image screen is blank. To add images to the screen (thereby making them available for use in labels), click **New Image from File**, then browse for and select an image file. When the image appears in the New Image screen, you can select it and click **OK** to place the image.

Curved Text
Click to place a text box on the artboard that follows the curvature of the disc. For additional text editing options, see "Palette" below.

Background
Click to place a background on the arboard. Backgrounds differ from "New Images" in that they appear "behind" any images or text placed on top of them.

Palette

Use the palette of the Label Designer to format items placed on the artboard.

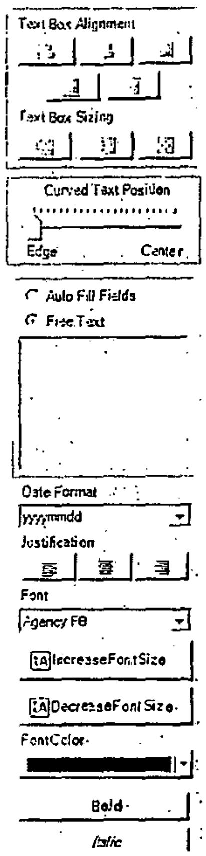

Figure 4.6 Palette on the Label Designer

Text Box Alignment
You can align one or more text boxes to another text box. Select the first text box on the artboard to serve as the anchor to which other text boxes will be aligned. Hold down the **Ctrl** key and click one or more other text boxes in succession. Click one of the textbox alignment buttons to align all selected text boxes to the anchor text box. You can align lefts, centers, rights, bottoms, or tops.

Text Box Sizing
Repeat the procedure for alignment above, but click one of the sizing buttons. All selected text boxes conform to the size of the anchor text box. You can size by width, height, or both.

Curved Text Position
Select a curved text box on the artboard, then move the slider between *Edge* and *Center*. The text box moves toward or away from the center.

Auto Fill Fields
Select a text box on the artboard, select *Auto Fill Fields*, then select a field in the Autofill list. When the label is printed, the text box is automatically filled with the corresponding information from the study being burned.

Free Text
Select a text box on the artboard, select *Free Text*, then type text in the *Free Text* list. The text appears in the selected text box.

Date Format
If any text boxes contain auto fill fields, you can select a format in which the date will appear.

Justification
Select a text box on the artboard, then click a font alignment button to left-, center-, or right-justify the text.

Font
Select a text box on the artboard, then select a font from the list. The text appears in the selected font.

Increase/Decrease Font Size
Select a text box on the artboard, then click **Increase/Decrease Font Size**. The text increases or decreases in size accordingly.

Font Color
Select a text box on the artboard, then click **Font Color**. Select a color for the text.

Bold
Select a text box on the artboard, then click **Bold**. The text is set in boldface type.

Italic
Select a text box on the artboard, then click **Italic**. The text is set in italic type.

5 Burning Reports

MediaWriter can include DICOM structured reports when burning studies to media. To start using this function, click *Settings > Reports*. The Reports Configuration dialog box appears. Enter settings as described below, then click **OK**.

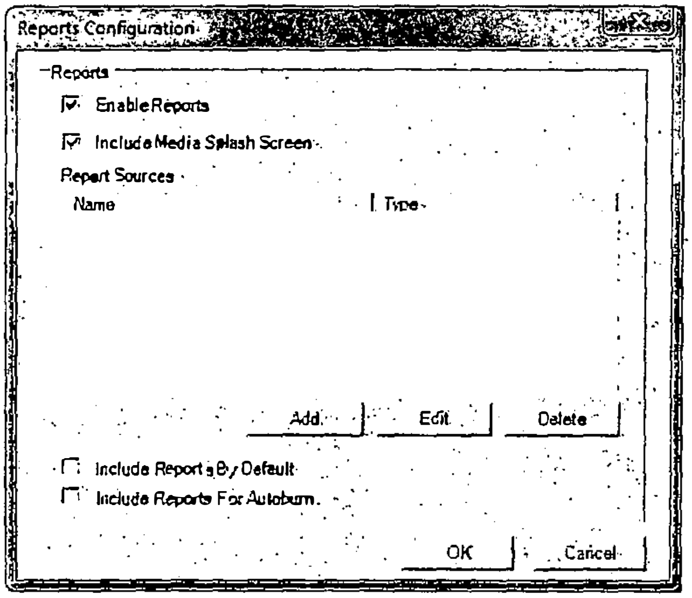

Figure 5.1 Reports configuration dialog box

Enable Reports
Select to turn the report burning function ON and OFF. When selected, an "Include Reports" check box appears in the the Burn Confirmation dialog box.

Include Media Splash Screen
Adds a splash screen to the report.

Include Reports By Default
Select to automatically include reports in burn jobs unless the user removes them. When selected, the "Include Reports" check box in the Burn Confirmation dialog box is selected.

Include Reports For Autoburn
Select to include reports when using the Autoburn function.

Adding a Report Source

In order to make reports available to MediaWriter, you must specify one source of the reports.

1 Click **Add**.

The Report Source dialog box appears. The appearance of the dialog box differs depending on the item selected in the Source Type list. Figure 5.2 shows the default appearance when DICOM is selected.

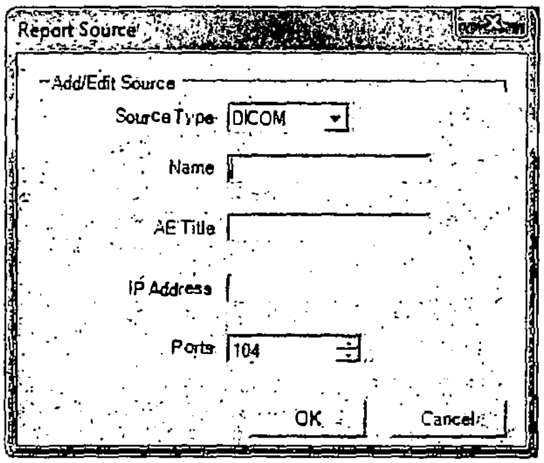

Figure 5.2 Report Source (DICOM) dialog box

2 In the *Source Type* list, select *DICOM*, *Folder*, or *Custom*.

DICOM
A DICOM compliant archive, such as a PACS.

Folder
A folder on a local or network drive.

Custom
A customized source, requiring you to specify the location of a configuration file.

3 Enter the required information in the boxes. For DICOM sources, enter the name, AE title, IP address, and port of the source. Click **OK** to enter the information and close the dialog box.

4 Follow the procedure to burn studies. In the Burn confirmation dialog box, select the *Include Reports* check box.

6 Decrypting and Viewing Studies from Media

Studies that have been burned to media (CD, DVD, or USB memory) by MediaWriter can be viewed on a PC. If the studies were encrypted at burn time, they cannot be viewed until they are decrypted. Choose the decryption procedure in section 6.1 or 6.2 depending on which viewer program you have available. Often, the viewer program is included on the medium at burn time.

6.1 Decrypting Studies with GEARView Basic

1 Place the medium containing the studies you wish to decrypt into the CD-ROM drive or USB port of the PC. The decryption dialog box in figure 6.1 should appear automatically. If it does not, use Windows to navigate to the medium, then locate and run the file *gearview.exe*.

2 Enter the password specified in the Burn Confirmation dialog box when the studies were originally burned.

3 Click one of the following buttons.

View
Studies are decrypted, then **GEARView Basic** opens and displays the studies (see section 6.3).

Export
Studies are decrypted, then you are prompted to select a destination folder into which the decrypted studes will be copied. Once studies are copied, you can open them for viewing with **GEARView Basic**. Exporting studies to a hard disk allows for faster viewing performance.

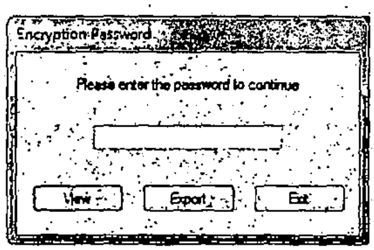

Figure 6.1 Decryption using GEARView Basic

6.2 Decrypting Studies without GEARView Basic

1 Place the medium containing the studies you wish to decrypt into the CD-ROM drive or USB port of the PC. The decryption dialog box in figure 6.2 should appear automatically. If it does not, use Windows to navigate to the medium, then locate and run the file *MediaWriterMediaDecryptor.exe*.

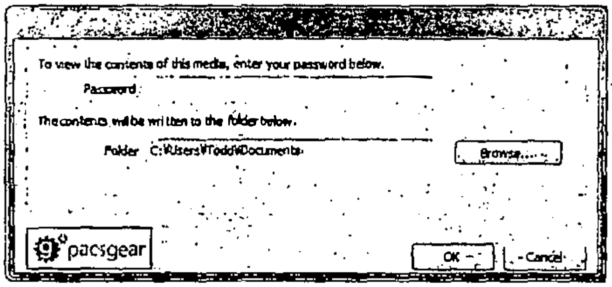

Figure 6.2 MediaWriter decryption dialog box

2 Enter the password specified at burn time.

3 Browse for and select a destination folder, then click **OK**. Two subfolders are created automatically: one within the specified folder (named "MediaWriterCDs"); and another subfolder within that subfolder. Copies of the studies from the medium are decrypted and placed in the second subfolder. For example, if you specify `C:\` for the destination folder, the files are decrypted and copied to:

C:\MediaWriterCDs\ MWCD_xxxxxxxxxxxx\ (where *xxxxxxxxxxx* is the current time and date).

If you decrypt another medium, or the same medium again, a new subfolder "MWCD_yyyyyyyyyyy" is created under C:\MediaWritersCDs. Note that the original studies on the burned medium remain encrypted.

6.3 Viewing Studies

If studies on a burned medium are not encrypted, or if they have been decrypted as described in section 6.1 above, they are ready for viewing. After you decrypt studies, in many cases **GEARView Basic** will start and display studies automatically. To view studies:

1. Place the medium containing the studies you wish to view into the hard drive or USB port of the PC. **GEARView Basic** starts and displays the studies.
2. If **GEARView Basic** was included on the medium at burn time but does not start automatically, use Windows to navigate to the folder containing the decrypted studies and then run the file *gearview.exe*.

   If **GEARView Basic** was *not* included on the medium at burn time and is not installed on your PC, a different viewer must be used. Consult the documentation for your viewer on how to open and view the studies.

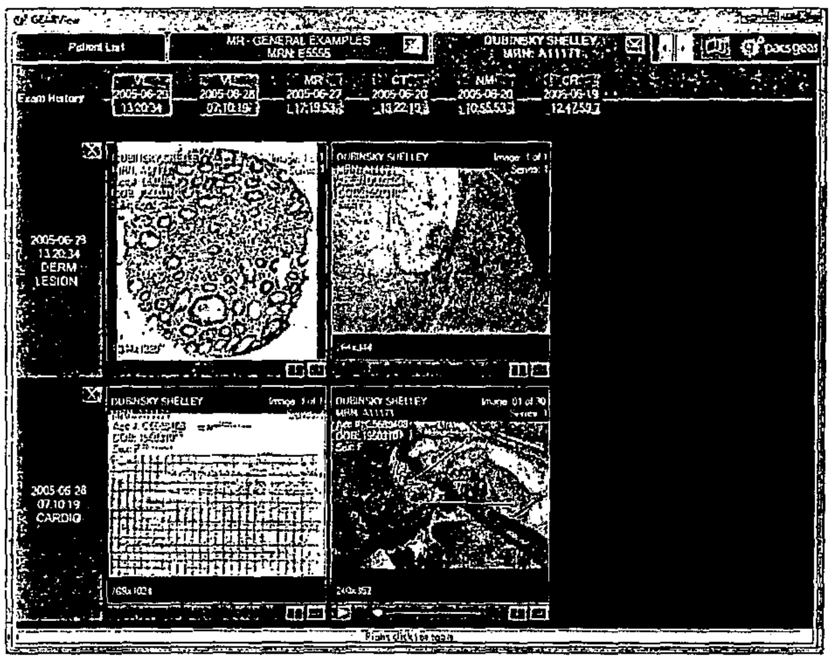

Figure 6.3 Studies opened in GEARView Basic

7 Working with the Server

MediaWriter contains several server related functions that are described below. These functions are only available to users logged on as the administrator ("admin"). To log on as the administrator, either click *File > Login As Admin* or click *File > Logout*, then type `admin` as the user name in the logon dialog box and leave the password field blank.

Checking the Connection with the Server

The connection status, server name, and port are displayed in the status bar at the bottom left of the program window.

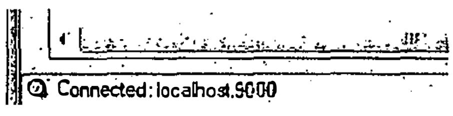

Figure 7.1 Server connection indicator

Checking the Server Status

When connected to a server you can check its status by clicking *File > Server > Status*.

Viewing Server Logs

You can view logs of server activity by clicking *File > Server > Logs*.

Automatic Server Restart

MediaWriter will automatically restart the server if certain software- or system-related changes have occurred. When this occurs, a confirmation dialog box appears. Unless study data is currently being acquired by MediaWriter, click Yes.

Restarting the Server Manually

If for any reason you need to restart the server manually, you can click *File > Server > Restart*.

Logging Off the Server

When you first start MediaWriter you are required to log on to a server. However, if you wish to work offline you can log off the server at any time by clicking *File > Log Off*.

8 Managing Users

MediaWriter allows you to set up multiple program users, each with different logon passwords and administrator privilege assignments. You can set up users either with Active Directory/LDAP, or manually by entering local user information.

Entering Settings in the Manage Users Dialog Box

1 Click *Settings > Users.*

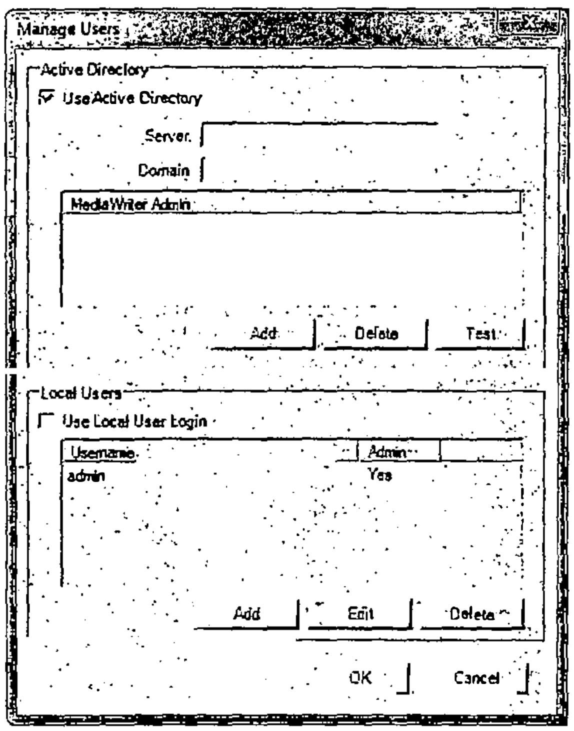

Figure 8.1 Manage Users dialog box

2 Type or select parameters based on the descriptions below, then click **OK**.

Using Active Directory/LDAP

Active Directory/LDAP stores user information on a server and acts like a phone book, providing a centralized logon service for Windows-based clients. If your PACS has an Active Directory/LDAP server, you can use the procedure below to configure users. Otherwise, MediaWriter lets you set up and maintain local users with encrypted passwords.

1 Select the *Use Active Directory* check box.

2 In the *Server* box, type the name of the LDAP server.

3 In the *Domain* box, type the server domain name.

Adding an Active Directory User

1 In the *Active Directory* area, click Add.

A dialog box for adding a new user appears.

2 To grant administrator privileges, select the *Admin* check box.

3 In the *Username* box, type in the user name and click **OK.**

Deleting an Active Directory User

In the *Active Directory* area, under *Username*, select a user to delete and click **Delete.**

Testing an Active Directory User's Password

1 In the *Active Directory* area, under *Username*, select the user whose password you wish to test.

2 Click **Test.**

A dialog box appears prompting you for the password.

3 In the *Enter Password* box, type the password and click **OK.**

A message appears indicating whether the password was entered and identified correctly.

Setting Up Local Users

If your PACS does not support Active Directory/LDAP, of if you prefer not to use it, you can configure local users with the procedure below. Note that you cannot use both Active Directory/LDAP and local users during the same session.

1 Select the *Use Local User Login* check box.

Adding a Local User

1 In the Local Users area, click **Add**.

A dialog box for adding a new user appears. Enter the following settings as needed.

Admin check box
Select to grant the new user administrator privileges.

Username
Type the name of the new user.

Password
Type the user's password.

Confirm Password
Retype the password.

2 Click **OK**.

The new user appears in the local users area of the Manage Users dialog box.

Editing a Local User

1 In the Local Users area, under Username, select a user name and click **Edit**.

The Add/Edit form above appears.

2 Edit the information in the boxes and click **OK**.

Deleting a Local User

1 In the Local Users area, under Username, select a user name and click **Delete**.

9 Other Settings and Functions

9.1 Audit Logs

MediaWriter's audit logs contain messages with detailed information about the application and how it was used. This information can be used to troubleshoot software problems. User messages contain time-stamped access and action information that is helpful for addressing HIPAA security concerns. To view a message in an audit log, simply click the log to view its contents.

Searching for Audit Logs

You can search for particular logs by performing the following procedure.

1 Click *File > Audit Logs.*

2 In the *Audit* list, select whether to search *By Patient* or *By Username.*

3 Type or select one or more of the search criteria described below, then click **Search.**

All logs matching the search criteria appear in the list in the lower part of the Audit Logs screen.

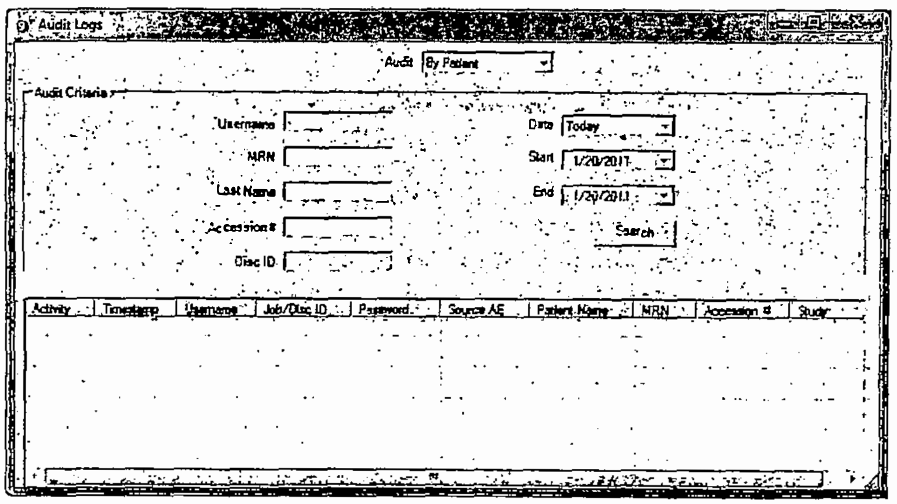

Figure 9.1 Audit logs screen

When By Username Is Selected

Username
Type the name of the user logged on when activity occurred.

Date
Select the range of dates of activities to search for. If you select Range, specify a range of dates by typing or selecting them in the Start and End boxes.

When By Patient Is Selected

MRN
Type the MRN of the patient.

Last Name
Type the last name of the patient.

Accession #
Type the accession number of the study.

Date
Select the range of dates of activities to search for. If you select Range, specify a range of dates by typing or selecting them in the Start and End boxes.

9.2 Auto Refresh

Use the following procedure to cause MediaWriter to refresh the Current Jobs tab automatically at specified intervals.

1 Click *Settings* > *Auto Refresh*.

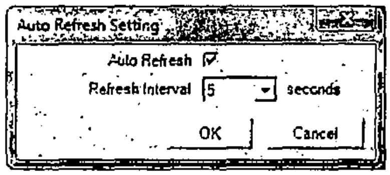

Figure 9.2 Auto refresh settings dialog box

2 Enter the following settings as needed then click **OK**.

Auto Refresh
Select or clear to turn auto refresh ON or OFF. You can also right-click in the Current Jobs tab and click *Auto Refresh Off* in the shortcut menu.

Refresh Interval
Select the desired interval.

9.3 Viewing the User's Manual, Product Information, and Software License

Viewing the User's Manual

1 Click *Help > User Manual*.

The user's manual is displayed in PDF format.

Note: Adobe Acrobat Reader version 6.0 or later is required to view the help file. Acrobat Reader is available for download free of charge.

Viewing Product Information

1 Click *Help > About*.

Viewing and Editing the Software License

1 Click *Help > About*.

If you are using this program for the first time or if the conditions of your software license have changed, you can enter or change the system ID, product key, and expiration date of the software as needed.

2 Click **Change**.

3 Edit the product key and expiration as needed (the system ID cannot be changed), then click **Close**.

pacsgear

10 Support

At PACSGEAR, your success is our success. If you have any questions or problems, please do not hesitate to contact us.

Customer Support (Americas, Asia-Pacific):

+1 925 225 6100 (8:00 am to 5:00 pm Pacific Time).

support@pacsgear.com

Customer Support (Europe, Middle East, Africa, Russia):

+49 (0)89450 807 600 (08:00 to 17:00 Central European Time).

support@pacsgear.com

MEDIMAGE®

THE IMAGE MANAGEMENT SYSTEM

ACOM.Convert

DICOM Archiving & Viewing Station

Software Vers. 4.42

Date of issue: 09.05.1999

CE

User-Manual

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VEPRO

COMPETENCE IN IMAGING

Sorna00048

Exhibit 240

Important Information:

For the administrating of the system you need to enter a password.

This password =

service

Please take this page out of the manual, if you do not like that the user is able to work in administrator mode !

Table of Contents

Quickstart

Viewing a DICOM CD

Insert a DICOM-CD into the CD-ROM drive.

Click on the CD-ROM symbol in the Standard Toolbar, to obtain an icon preview or a DICOM File Selection Dialog Box of all the picture-sequences on the DICOM-CD.

Display a picture-sequence by double-clicking on its representative icon in the Icon preview.

With the Image Controls you can choose how you wish to view the sequence (by animation- or by viewing single images) or alter the contrast and brightness.

With a single mouse-click on the symbol at the top right of the active sequence window you can close the sequence currently being displayed.

To exit the application click on the symbol in the Standard Toolbar, or on the symbol at the top right of the program window.

WARNING - If too many films are displayed at one time, the following problems may arise:

If too many large sequences are open in the application, they may under certain circumstances not all fit into the computer's main memory (RAM). This means that the operating system will swap the overflow into the main-memory when the overflow pictures need to be displayed. This swapping leads to a serious deterioration in performance when several sequences are animating simultaneously.
Solution: Close sequences when they no longer need to be shown (this removes them from the computer's main memory). When you really must display several large sequences on the screen at one time, limit the number that are animating to as few as possible by stopping the animation (see: Viewing Single Images).

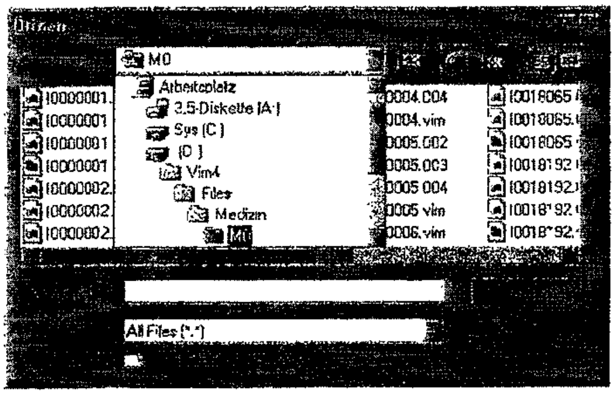
Displaying archived images from the IMAGE-Archive

- Click on the symbol on the Standard Toolbar. In the open window enter a patient name, select with a douple click the study then all icons regarding this study are displayed. With a douple click on this icon, the images/sequences are displayed.

Displaying images from any media and/or directory

Click on the symbol on the Standard Toolbar. Select a drive, the directory and the file with a double click. Image files with following extension can be displayed:

DCM, VIM, 002 – 999, TIF, BMP, PCX, JPG etc.



You have the same image/film manipulation possibilities as when displaying DICOM-CDs.

Operating

Notice:

In cases of loss of power supply the UPS unit will provide the power. If the external power supply is not working again after five minutes (indicated by an audible signal during the loss) the system has to be shut down.

The User Interface

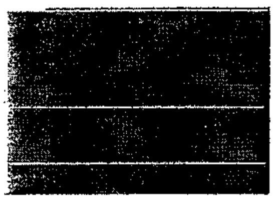
Menus

During image display the menu bar shows five menus:

File, Edit, View, Window and ***Help***

If no image is displayed the menus "***Edit***" and "***Window***" are suppressed.

File:



Open, open a picture or a film sequence from any drive or directory

Open DICOM CD-ROM, open an Icon-preview of a DICOM CD .

Open Archive , opens an archive and shows the text-based representation of the contents of this archive.

Close, close the currently active sequence. Only available if there is a sequence currently open.

Print Image, prints the image being displayed in the active window. Only available if there is a sequence currently open and if the selected sequence is not currently animating.

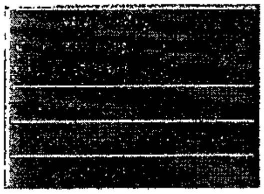
Printer Setup, change the currently active printer.

Exit, exit the application.

Edit:

Copy, copies the current image to the clipboard. Many of the current available text editors and imaging systems allow to import images from the clipboard.

View:



Standard Toolbar, turns the Standard Toolbar on (ticked) / off

Image Controls, turns the Image Controls toolbar on / off

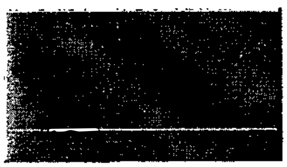
DICOM Icon Preview, turns the DICOM Icon Preview window on / off.

Options..., opens the Options dialog box.

Video Speed Test at Startup, turns on/off the Video Speed Test that appears when the application is initially launched.

Enable Delete, enables the deletion of images or series (Enter password).

Window:



Cascade, display the windows overlapping

Tile Horizontally, tile the windows above each other,

Tile Vertically, tile the windows side-by-side.

Arrange Icons, assembles the windows that are iconified, at the bottom left of the application window,

Display Actual Size, displays the active window in real (100%) size. If this size does not fit the application window for displaying sequences the active window will be displayed as large as possible.

Sequence Windows, several entries may be displayed here. They serve as a fast way to select a particular window, especially if the windows are on top of each other. In the example above, the sequence with the filename XA000005 is in the active (ticked) window, and it the only file/window open.

Help:

Help Index, displays the on-line help file.

About the Viewing Software, displays version information of the application.

Standard Toolbar

Using the *View* menu option *Standard Toolbar* the standard toolbar (shown above) can be displayed/hidden. This may be useful if a larger area is required for displaying images.

The functions of the icons on the toolbar can also be accessed via the menus above.

Meaning and functions of the symbols (icons):

 Open an image or film file on a specified drive or directory (*File* menu option *Open*).

 Open an icon preview or the DICOM File Section Dialog Box for a DICOM-CD (*File* menu option *Open DICOM CD-ROM*).

 Open the archive (*File* menu option *Open Archive*).

 Prints the image in the active window (*File* menu option *Print*).

 Cascade all open windows (*Window* menu option *Cascade*).

 Tile horizontally all open windows (*Window* menu option *Tile horizontally*).

 Tile vertically all open windows (*Window* menu option *Tile vertically*).

 Try to display the active window in its real (100%) size. If this size cannot fit into the space the application window has for displaying sequences, then the active window will be displayed as large as possible (*Window* menu option *Display Actual Size*).

 Frame selection in the biplane version: You can display the first (frontal) frame only, the second only (lateral) or both simultaneously. Display of both frames is selected in the left-hand example

 Toggle the global 256-color palette between a palette with a wide range of colors, and the default gray-scale palette. See main section: Changing the Global Palette in 256 Color Mode

Note: This button will only appear if your Windows graphic mode is set to 256 colors.

 LVA (Leftventricular Angiogram). Enters the LVA module. This optional module is only available, if the LVA module is actived on the dongle.[1]

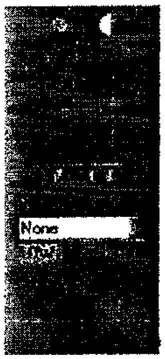
 Exit the application (*File* menu option *Exit*).

[1] This option is not available for Siemens customers.

Image Controls

With the *View* menu option *Image Controls* the Image Controls toolbar can be shown/hidden. This is often useful when a larger area is required for displaying images.

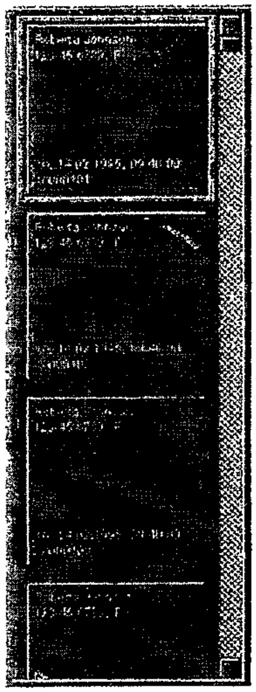
The most upper region of the Image Controls consists of two sliders which allow the adjustment of the brightness and contrast of images. The region underneath is for image processing and controlling animation or stepping frame-by-frame through the scene.



The block of buttons on the very bottom controls functionality for sequences .

DICOM Icon Preview

The DICOM Icon Preview window can be hidden with the *View* menu options. To hide the icon bar is often useful to view images who needs more space to display.



With the DICOM Icon Preview you have an overview of the images/sequences available on the currently used archive (Network/CD-ROM). Sequence / image information such as patient name, ID can be displayed on each icon.

To load a DICOM Icon Preview click on the or the symbol, or select Open DICOM CD-ROM / OPEN ARCHIVE from the File menu.

Alternatively, you can also load any DICOM directory files (named DICOMDIR) into the preview window by clicking on the normal symbol, or through the *Open* option on the *File* menu.

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There are several methods with which the required sequence can be selected for display -

With the mouse:

Use the scrollbar right of the icons to get the required sequence icon.

Double-click with the left mouse button on the icon to start loading this sequence.

With the keyboard:

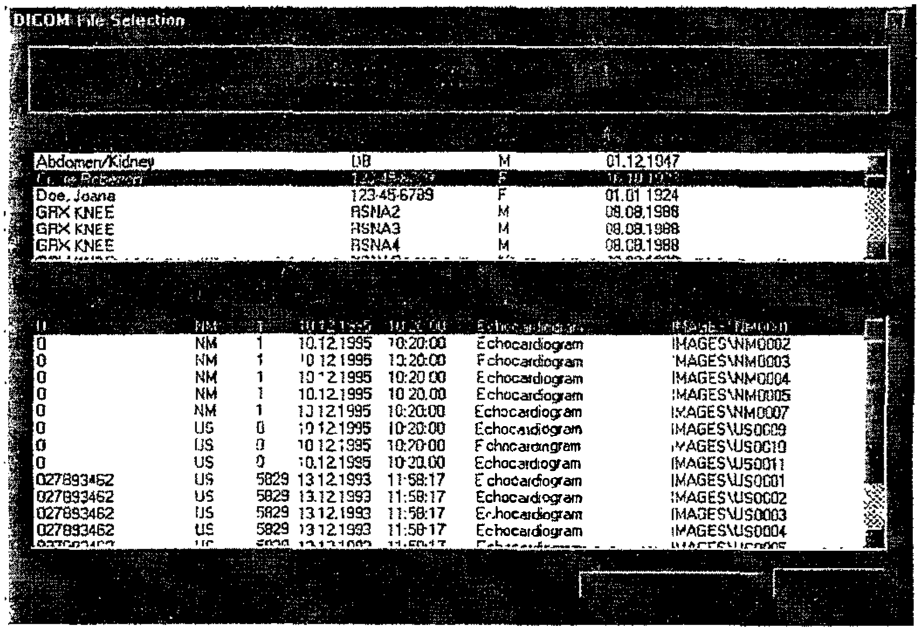
With the up and down cursor keys (↑, ↓) the position of the green frame around the required sequence icon can be changed.

Press the RETURN key (↵) to start loading the sequence.

It is easy to change the brightness or contrast of the icons. Please see the section entitled Changing Brightness/Contrast.

The DICOM File Selection Dialog Box

The DICOM Icon Preview window can be hidden with the *View* menu option *DICOM Icon Preview*. When it is turned off the following dialog box will appear in its place when a DICOMDIR file is opened:



This window gives a text-based representation of the contents of the DICOMDIR file. Select a patient in the upper list - the lower list then will be filled with all available studies of this patient - then select one of the studies from the lower list.

The Select button will open the currently selected study.

Keyboard Shortcuts

Many mouse functions are duplicated by a keyboard shortcut. Here is a list of all these shortcuts:

Animation Controls:

Key	*Action*
Spacebar	Stops, starts a sequence animating.
←	Go to the previous image in the sequence (if the sequence is not animating).
→	Go to the next image in the sequence (if the sequence is not animating).
+	Increase the speed of the animation (the frame rate)
-	Decrease the speed of the animation

DICOM Icon Preview Controls:

Key	*Action*
↑	If icons are present in the DICOM Icon Preview Window, then this will move the green selector box an icon *higher*.
↓	If icons are present in the DICOM Icon Preview Window, then this will move the green selector box an icon *lower*.
Enter (↵)	If icons are present in the DICOM Icon Preview Window, then this will open the file of the icon currently selected by the green selector box.

Sequence Selection Controls:

Key	*Action*
Ctrl-Tab	If you have more than one sequence/image window open, then this will toggle the focus between them.

Note: The following shortcuts may be changed in subsequent versions of the Viewing Software

Image Processing Controls:

Key	*Action*
Q	Increases the *brightness* of the currently selected sequence.
A	Decreases the *brightness* of the currently selected sequence.
W	Increases the *contrast* of the currently selected sequence.
S	Decreases the *contrast* of the currently selected sequence.

Displaying Sequences

Sequences acquired in Monoplane Mode

The sequence acquired in the monoplan mode (single shot version) are represented as an Icon for each sequence in the DICOM icon preview

Load a DICOM icon preview.

Use the scrollbar right of the icons to get the required sequence icon.

Double-click with the left mouse button on the icon to start loading this sequence.

Sequences acquired in Biplane Mode

The sequences acquired in Biplane mode (double shot version) can be represented by one icon for both planes of each sequence or as two individual icons for the two planes of each sequence depending on the recording method. Both planes can be displayed simultaneously side by side being synchronized.

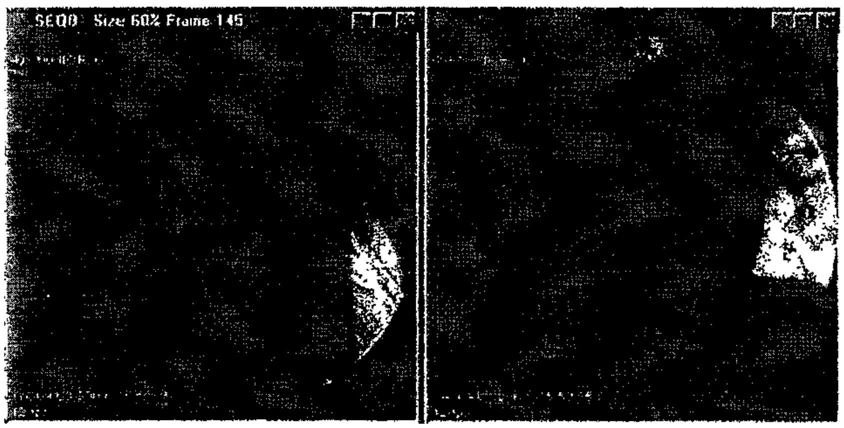
Load a DICOM icon preview.

Use the scrollbar right of the icons to get the required sequence icon.

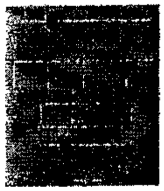
Double-click with the left mouse button on the icon to start loading the first plane of the sequence.

Double-click with the right mouse button on the same icon to start loading the second plane of the sequence if the icon represents both planes. If the second plane is represented by an additional icon, double-click with the right mouse button on this icon to start loading the second plane of the sequence.

Both sequences are synchronized displayed side by side. Changes for example of position and size also closing of window affects both display windows.



Animating Sequences



To start Animation Mode, the Play/Stop button must be pressed (this button will remain depressed while the film is animating).

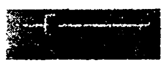
The animation can be stopped by a click on the same button.

Stop and start can also be accomplished using the spacebar on the keyboard.

When a sequence is loading the following button is active. Pressing the button between loading a sequence no more images from the sequence will be loaded. The images loaded up to that point may then be manipulated in the normal manner.

The method of animation can be select with one of the following buttons:

- play the film *backwards*,
- play the film backwards and forwards simulating a *pendulum*'s motion.
- play the film *forwards*.

As the sequence animates, the slider  indicates the current image (frame) number.

The slider  alters the speed of animation (in frames per second - fps), also known as the *frame-rate*. In this example the sequence animates at 12 frames per second. Grab the pointer on the slider and drag it to the required position. Speed-rate adjustments may also be made using the + and - keys on your keyboard.

As a sequence loads this slider will automatically be set to the recommended animation rate as stored in the sequence itself.

High Frame Rates

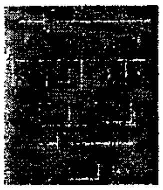
If the frame-rate is set to a high level (relative to the computer's capacities) then images may have to be skipped during the animation to maintain the requested speed. This is often not serious, but for advice see the section entitled 'Skip frames to maintain play speed' in the Options section of this help file.

When a frame has been skipped a red square will appear in the corner of the image window as shown below:

As an alternative to animating the DICOM sequences, sequences may also be viewed manually, on a frame-per-frame basis. See: Viewing Single Images.

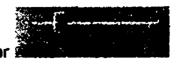
Viewing Single Images

The manual display of single images in a sequence, as opposed to animating sequences, is achieved through the use of the Image Controls, as shown below.



To use this viewing method, if the film is animating the Play/Stop button must first be pressed to stop the animation. This may also be achieved with a press of the spacebar on the keyboard.

There are many ways to view a particular image in a sequence:

you can move the frame pointer  to the required image position by pressing down the left mouse button on the pointer.

with a mouse click on the button or by pressing the ← cursor key on the keyboard the previous image in the sequence will be displayed.

with a mouse click on the button or by pressing the → cursor key on the keyboard the next image in the sequence will be displayed

Note: The currently displayed image number is always shown in the title bar of the sequence window.

Operations on Sequences

The following buttons in the image Display Controls are for operating on sequences:

When pressing the button:  all sequences on a CD are automatically loaded and animated when viewing a DICOM CD-ROM. How many times a sequence is played back is defined by a value in the options dialog. Furthermore, the automatic loading and animation process of sequences can be started when the button is pressed and a sequence is selected. In this case, starting with the selected sequence, all other following sequences are loaded and displayed.

Note: When „automatic loading of sequences at program startup" is activated in the options dialog to step manually through the set of sequences, the following two buttons are provided:

 Show previous sequence.

 Show next sequence.

If you have a still image between your sequences, the automatic playback mode will be stopped till you switch to the next sequence.

Changing Brightness / Contrast - Optimization

The brightness and contrast of the images in a sequence may be altered using the brightness and contrast sliders on the Image Controls toolbar, as shown below.

All alterations to the brightness and contrast affect the whole sequence, and not just the displayed image.

The *brightness* is adjusted using the left of the two sliders, and has a range from -127 (dark) to +127 (bright)

The *contrast* is adjusted using the right of the two sliders, and has a range from -127 (low contrast) to +127 (high contrast).

You can also change the contrast and brightness by pressing the right mouse button while moving the mouse in the sequence right and left for contrast and up and down for brightness.

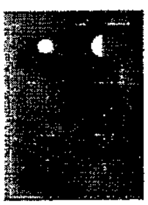
Contrast optimization

Note: Automatically always the contrast optimization feature is as an default switched on. This feature allows „on the fly" to analyze an image / sequence and displays it always with the best visible contrast – without loosing information. To switch off this feature press the button.

To enable once more this feature – only double click on the displayed icon.

Image reversion

Press the button to get an inverted image displayed.



If the Ctrl key is held down, then the two sliders will display the settings for the DICOM Icon Preview icons (see above diagram - note the frame around the controls). While the Ctrl key is held down, the contrast and brightness settings for the icons may be altered with the mouse.

Display Actual Size

When the symbol is clicked or the option *Display Actual Size* from the *Window* menu is selected, then the program will try to display the images in the active window at the images' real (100%) size. This will be achieved by enlarging or shrinking the window surrounding the images.

If the image to be displayed is too big to fit into the area available for display, then the program will display the image as large as possible.

To make as much space for an image as possible, you may wish to hide one or more of the *Standard Toolbar*, the *Image Controls* toolbar or the *DICOM Icon Preview* by turning them off from the view menu. You can then maximize the image window within the application by clicking on the button at the top right edge of the image.

When an image cannot be displayed at 100% size, then the computer's graphic resolution should eventually be increased to accommodate this size. A new graphic card may be required. This is especially the case when a standard 512 x 512 cardiology image cannot fit on the screen.

Image Window Organization

When several sequences are being displayed simultaneously, then the non-minimized sequence windows can be tidily arranged by a single click on a symbol on the Standard Toolbar by the following methods:

Cascade	(*Window* menu option: *Cascade*),
Tile horizontally	(*Window* menu option: *Tile Horizontally*) or
Tile vertically	(*Window* menu option: *Tile Vertically*).

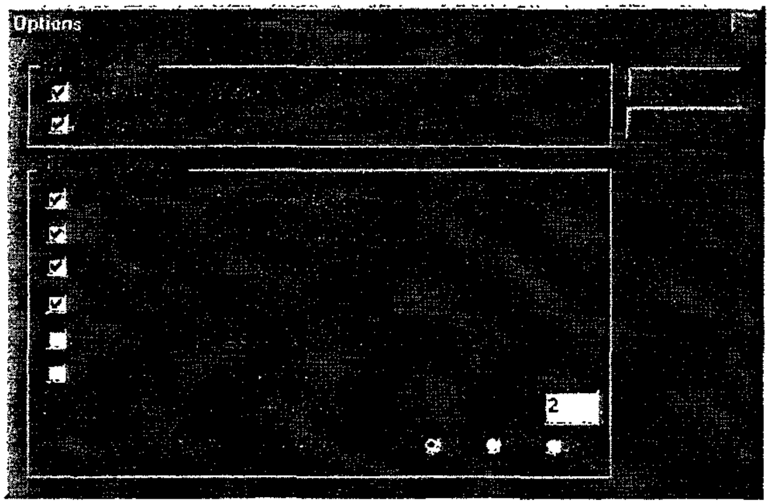
Arranging Minimized Image Windows

When several sequences are being displayed simultaneously, and at least one window has been minimized to the Xa000005 ... symbol, these minimized windows may be tidily ordered in the bottom-left of the program window by selecting the *Arrange Icons* option from the *Window* menu.

Viewing Operations with the Operation Panel [2]

The Operation Panel is an optional tool for easy and ergonomic viewing of images or sequences.

For using the Operation Panel it is recommended to set the option „Automatic playing of sequences" to inactive (not ticked): Select the option *Options* from the *View* menu and deactivate the Automatic playing of sequences.



For correct functionality of the operation panel it is to be configured.

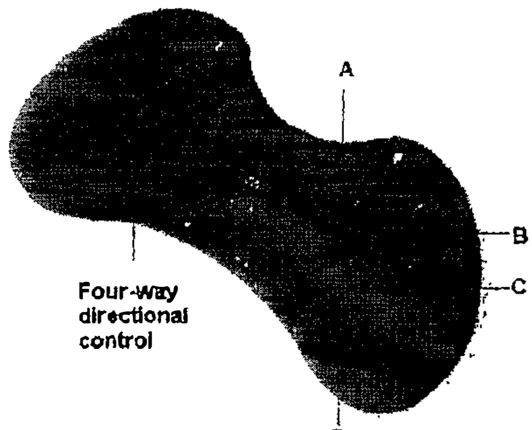
Configuration of the Operation Panel

- Click on the „Start" button on the desktop
- Click on „Settings" – „Control Panel"
- Double-click on „Input Devices"
- Choose the game controller and click on the button „Settings"
- Click on the button „Calibrating" and follow the instructions on the screen
- At the end close the window by clicking on „OK".

[2] The operation panel is an optional accessory. This option is not available for Siemens customers.

Control Elements of the Operation Panel

On the joystick you have five control elements, four buttons signed from A to D and one four-way directional control.



In the further description the buttons are symbolized through their Capitals, the four-way directional control (D-Pad) options are abbreviated:

O↑	pressing D-Pad in the updirection
O↓	pressing D-Pad in the down direction
O←	pressing D-Pad in the left direction
O→	pressing D-Pad in the right direction

Select Mode

For the selection of sequences or pictures from the archive the controls give access to the following functionality (A and C are working as on/off switches):

A	Open archive / Close archive and display the chosen patient in viewing mode
B	Toggle between standard filters(predefined in the file vim.ini)
C	Open filter selection drop-down list / Close filter selection drop-down list and use selected filter
O↑	Browse upwards in the list (patient or filter selection)
O↓	Browse downwards in the list (patient or filter selection)

Viewing Mode

Notice:
Animation control functions are not working during the loading process.

For viewing sequences or pictures the controls give access to the following functions in the animation control:

A	Open archive /
	Close Archive and display the chosen patient in viewing mode (the former view will be automatically closed)
B	Stop / Start animation
O↑	Browse upwards in the icon preview and select the sequence immediately to be played
O↓	Browse downwards in the icon preview and select the sequence immediately to be played
C+O↑	Browse upwards in the icon preview and select the 2nd plane sequence for the biplane mode (double shot version); immediately start playing when C is released
C+O↓	Browse downwards in the icon preview and select the 2nd plane sequence for the biplane mode (double shot version); immediately start playing when C is released
D+O→	increase Animation speed in steps
D+O←	Decrease Animation speed in steps
O←	play the film backwards while pressed
	play the film backwards step by step when animation is stopped
O→	play the film forwards step by step when animation is stopped

Archive & Retrieval

VEPRO DICOM Distributor

To receive DICOM images from a modality the DICOM Distributor software must be installed at the computer system. In the Task Bar on the bottom of the WINDOWS screen

this control icon appears: 

It indicates that in the background a second application for DICOM receiving is running.

With a double click on this icon a control screen (window) comes up:

where beside the DICOM receiving messages and the Job list, four other major functions are available

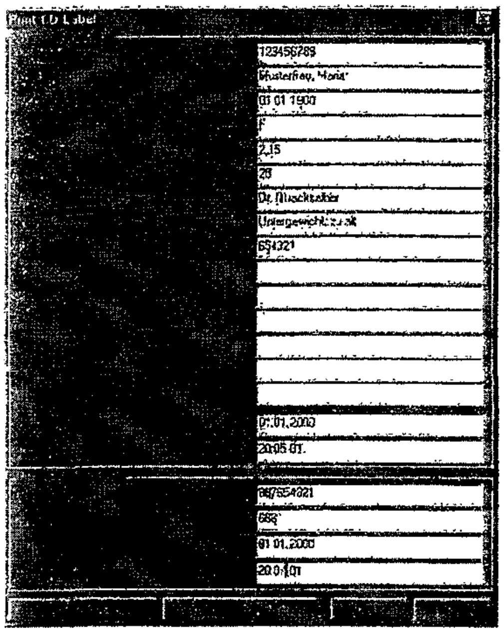
- CD-Copy
- CD-DVD Label Print
- DICOM Echo
- Failed DICOM Transfer

CD-Copy

Insert a blank CD into the CD-Writer and the source CD into the CD Reader, than press the CD-Copy button . Depending on the data size ano the speed of the CD-Wnter it could take from a couple of minutes up to 20 minutes to create a new CD. After the CD is copied, a verification of the CD is carry out. In case of success (displayed under the TAB "Jobs") the CD is automatically ejected from the CD-Reader Slot.

CD-Label Print

To print a new CD-Label (for copied CDs), press this button. Make sure that the labels are inserted in the right printer slot and in the right direction. Following window comes up, to change the patient or migration data, printed on the CD-Label:



In this dialog box two areas are available to enter data for printing either a patient label or a label for a migration medium. In the upper area the patient information is entered, in the lower area the correct data for a migration media.

After entering the correct data, a CD-Label is printed on the connected printer (if available).

Send DICOM Echo

To check if the DICOM modality is connected and responding to the Archiving System, press this button. If the physical connection and the configuration for the DICOM transmission is correct a message is displayed. If there is any failure mentioned check your DICOM TCP-IP address, the DICOM Port Number, and the DICOM AE-Title of both systems (Sender and Receiver).

NOTE: If the Archiving System is connected directly to the DICOM modality (without using a Network-HUB or SWITCH) a "Crossover" network cable must be used for a connection.

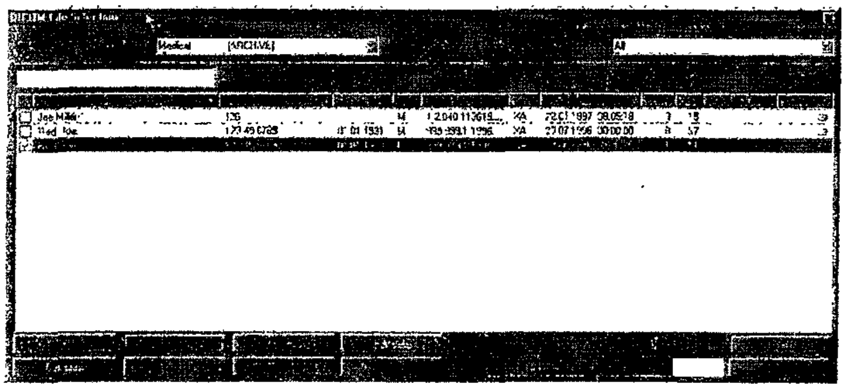
Failed DICOM Transfer

On selecting this symbol  a window opens displaying the names of the patient studies not transferred to the DICOM network due to a transfer error.

Here you have the possibility to select a patient study and send it again. To cancel the transfer of the patient to the DICOM network, the patient can be deleted from the list.

Display images from the archive

To access the archive, click on the symbol in the standard toolbar or choose *File* menu option *Open Archive*. The following dialog box appears:



("Space used from archive" gives the percentage of disk space used of the hard disk drive the archive is on)

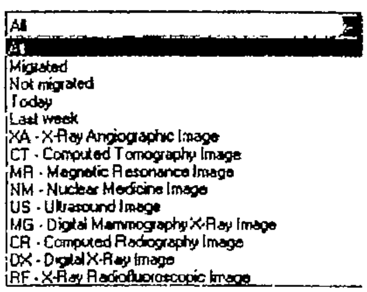
Selected Archive

If different archives (local drive, server) are configured you may choose the archive you want to retrieve data from.

Selected Filter

Several filters are available for the database. You can choose one of the listed filters to display only the sequences which fit the criteria. For example all studies from any patient are displayed using the filter "All". If only the non-migrated (not yet archived on CDs or DVDs) should be displayed change the filter to "Not migrated". As a result you see all studies which need to be migrated to a long term archive media.

Please ask your system administrator if other filters must be defined especially for you:

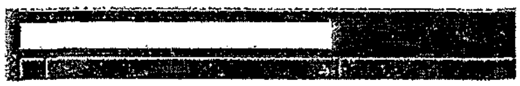


Search criteria

Clicking the column title activates the search in this column (display with green background) and sorts the data ascending. The next click, sorts this column descending. In standard configuration the following columns are given:

("Type" indicates the modality as given in the DICOM file of the data set, "Count" gives the number of images in a series, "Size" gives the size of the series in MB, "Medium ID" gives the (unique) ID of the migration medium, if the data set is already migrated, "Status" see paragraph *Archiving Status* below)

You can directly jump to a data set by entering data into the data field above the archive. E.g. you may activate the column "Patient ID" and enter "34587" into the data field. The data set with a Patient ID closest to "34587" (e.g. 34563) will be highlighted



Double clicking the highlighted study gives the preview ICONS of this patient and the images or sequences can be displayed as usual.

Select patient

To get images or film sequences of a patient, select the corresponding patient from the list and click the button ***Select Patient***. Alternatively you can double-click the patient study in the list.

Create Media

Differences between Migrate to Medium and Create Patient medium

Migrate to medium

Migration copies all selected studies to a long term archive (CD / DVD) and creates a medium what MUST be used in the "shelf archive" -- or into a "Jukebox".

Note: It makes always sense to create a copy of such a Migration Medium and store this at a other location for safety reasons.

After a successful migration in the status column a medium symbol is displayed and a migration no. (00001 – 99999) plus a migration ID is created for this medium.

Note: Only if a migration to a long term medium was made, the system is able to move out this study from the FIFO (First In First Out) archive.

Never take a migration medium as an exchange media to a third party – it is the only real archived medium for a later image retrieval and or for a database recovering.

Create patient medium

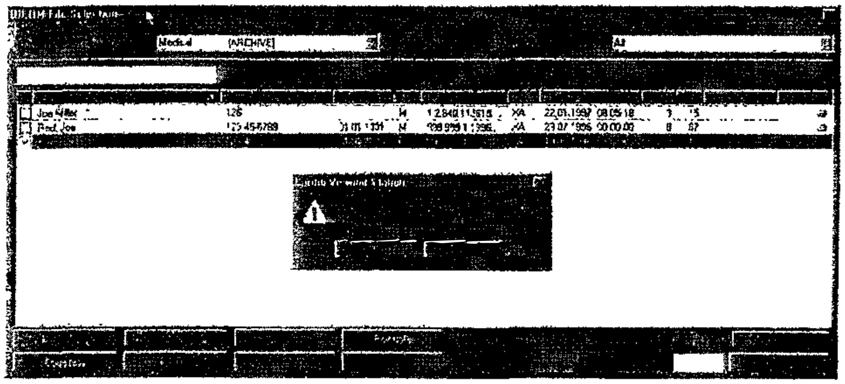
This function allows to create a medium with one, or several patients on it. Automatically the viewing software is also copied to this medium allows –a patient or an other hospital -- to view this images with inserting this medium into a normal PC.

Note: This functionality does not change any archive status– it is only a copy of the archived data on the disc.

Migrate to Medium

If one or several studies are to migrate to a long term archive media like CD or DVD (optional) then each of the studies must be marked with a click on the square box in front of the patient name.

For writing CDs you can mark up to 600 MB data, for writing DVDs you can mark up to 2,5 GB totally.



After the successful migration a Medium Label is printed with a Medium no., a Medium ID and the date and time of the migration. The Media ID has 10 digits. The first 5 digits are a number continuous increasing with every successful migration. The last 5 digits represent the serial number of this archiving system.

The Archiving system does not delete this studies from the local or central archiving disk after a successful migration to a long term archive media. The studies are always available in a "Cache" and are only moved out of the Cache in a FIFO (First In, First Out) manner, if the disc is full.

Never take a migration medium as an exchange medium to a third party – it is the only real archived medium for a later image retrieval and or for a database recovering.

Create a Patient Medium

If one or several studies should be copied to a medium like CD or DVD (optional) then each of the studies must be marked with a click on the square box in front of the patient name.

For writing CDs you can mark up to 600 MB data, for writing DVDs you can mark up to 2,5 GB totally.

☐ Red, Joe
☑ Red, Joe

After the successful copying a Medium Label is printed out with the name of the first patient study.

Note: With this copy of patient(s) studies the archiving status is NOT changed.

DICOM send

Sends the ticked data sets as DICOM files to the configured recipient (e.g. via a DICOM network to the archive server).

Add files from CD

Reads all DICOM files from the medium (CD or DVD) in the first configured CD-ROM drive and writes them into the archive.

Delete

To delete a patient study from the archive, you must enable this at first in the Menu Bar under the section *View* with the option *Enable deleting of series.* After entering a password studies can be deleted. Click on the patient study and press the *Delete* button. To disable the deletion possibility, click again the option *Enable deleting of series.*

Please ask your Archive Administrator for the correct password.

Edit data

To edit patient data click "Edit data". You will have to enter the password.

Data security is an important issue in medical data bases. It is recommended not to edit patient data unless it is absolutely necessary. Therefore the "Edit data" button can be set to inactive by the system administrator (and is set to inactive by default). Ask the system administrator if you need to edit patient data to activate the "Edit data" button.

Archiving Status

The status of the image archiving is displayed in the row "Status" :

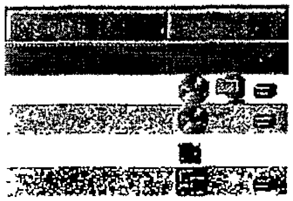


image online available

image online lossy compressed available, migrated to long term media

image online available and migrated to long term media

image series is not completely acquired

image online available, data was archived to a DICOM network

Compress

To store as much as possible studies in the archive, the lossy compression of images is offered. After pressing this button a decision for the compression ratio and the compressed archive period must be made. Three choices for a lossy compression are:

LOW compression (Ratio ca.: 8:1)	- no visible information lost
MEDIUM compression (Ratio ca.: 12:1)	- visible information could be lost
HIGH compression (Ratio ca.: 18:1)	- visible information is lost

Note: Generally all images are stored, after receiving from a DICOM modality, in a 2:1 lossless compression and are also migrated in a lossless mode on all long term archive media (CD / DVD).

Images cannot be compressed "lossy" on the Online storage, if they are NOT migrated to a long term archive media before. You recognize this migrated media, if they are marked with a official MEDIUM ID (by example: 00004 11227) – this means the fourth migration at station 11227.

Reorganize

Only in emergency cases, (if the database is corrupt or lost) this option is able to reorganize the complete database for image access. Please note:, this takes – depending on the number of migrated CDs/ DVDs, from several minutes to several hours, because – in worst case – all migrated media must be manually inserted and checked (if no jukebox is connected) to rebuild the complete database.

Do not acquire new data during the reorganization of the data base. The new images will be integrated into the data base at the place the reorganization process is working at the moment. That way the new images are dispersed through your old data . . .

Printing

Printing Images

To print the image currently displayed in the active sequence window, click on the symbol, or select the *Print Image* option from the *File* menu. The printing is carried out in the background.

Achieving the best possible print quality

To achieve the best possible print quality we recommend the following printer settings for black and white printers:

Printer resolution: Highest possible setting, for example 600 dots per inch (dpi)
Dithering: Coarse.

To change the printer settings to those stated above, the following procedure should be followed:
Open the Start Menu by clicking on the Start symbol in the bottom-left corner of the screen.

From this pop-up menu select the option Settings, then from the subsequent menu, click on the option Printers.

From the now-open printer list click once with the right mouse button on the printer you wish to use, then from the file menu select Configuration. The Configuration dialog box will now open.

At the top of the dialog are a number of „tabbed" options- Graphics, Device Options etc., click on the word Graphics. Now change the options Resolution and Dithering to the settings recommended earlier. After this is completed, click OK to finish.

Repeat the above processes for each printer you may wish to use with the Viewing Software.

Printer Setup

To select a particular printer, select the option *Printer Settings..* from the *File* menu. The standard Windows printer setup dialog box is then displayed.

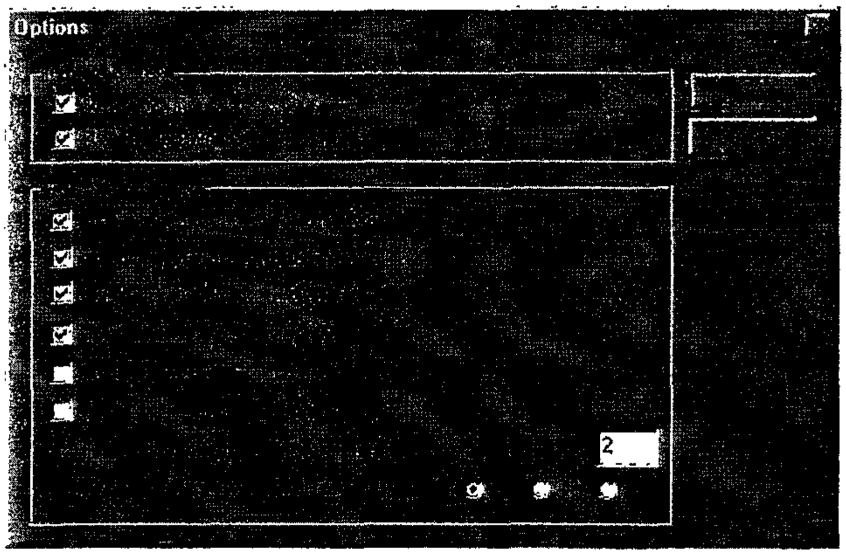
Only the printer type, paper size and orientation settings can be controlled, all other settings are ignored.

Note: See Printing images for additional information about printer settings and printer configuration.

Configuration

Options

Select *Options* from the *View* menu to configure the functionality of the program.



Tick options to activate:

Display sequence information: displays sequence information text on top of all open film sequences. For example: Patient name, ID, sex, study description etc.

Display icon information: displays sequence information text on the icons in the DICOM Icon Preview. For example; Patient name, ID, sex, study description etc.

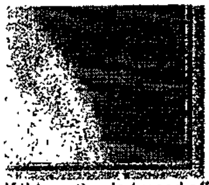
Load sequences and play immediately: sequences will start animating immediately after loading. See: Animating Sequences

Automatic contrast optimization while loading: all images / sequences are displayed with the best visible contrast –(as calculated from the viewing software).

Skip frames to maintain speed:
If the animation speed is set to a rate too high for the computer to maintain (this limit is set by the computational/display speed of the computer), this option helps to maintain the requested speed by skipping frames (images) if necessary. This may be important e.g. if a sequence has to be displayed at a rate of 50 frames per second for diagnostic reasons, though the computer does not support this.

Frame dropping is not so drastic as it sounds, and will often be unnoticeable. The greater the number of dropped frames, the more noticeable it becomes.

In an animated sequence a small red square in the bottom-right corner of the sequence window indicates if the previous frame was dropped to maintain the animation speed.



If this option is turned off the program will display every frame, and will attempt to animate as fast as possible up to the requested animation speed. The requested speed may be unobtainable with this method, depending on the speed set and the capabilities of the computer. For example, a sequence that should be displayed at 50 frames per second may only reach 30 frames per second.

Don't display sequences parallel: new opened sequences will replace the currently active sequence window, closing this 'old' sequence. This means that if you, for example, open six sequences one-after-another, only the last sequence opened will remain open in the application.

If this option is not activated (this is the default setting), each successive sequence opened is loaded into a new window, not replacing any existing window.

Useful Tip!: If you are opening sequences from the DICOM Icon Preview window, you may reverse this setting temporarily using the Ctrl key on the keyboard. This is managed by holding down the Ctrl key during the double-click on the sequence icon (see: DICOM Icon Preview).

Automatic playing of sequences: at program startup sequences will be automatically loaded one after each other.

Always load sequences in full screen mode: sequences are loaded in full screen mode automatically

Number of loops before next sequence: Number of animations in the the cine-loop, before the next sequence is loaded. This option only works with "Automatic playing of sequences" active.

Loading of BiPlane sequences in mode (A, B, AB): A: sequence A is displayed, B: sequence B is displayed, AB: both sequences are displayed simultaneously, when loading a BiPlane sequence.

Sequence Information

If the option *Display sequence information* is turned on, then information pertaining to each sequence is super-imposed over its images, as shown below.

This consists of patient information:

Name,

ID number, sex.

and information about the sequence/image:

Recording method, recording date, recording time,

study description and recommended display rate, if there is one (in frames per second).

The title-bar of the window will always display:

the sequence name,

the percentage of the original picture size in which the sequence currently is displayed,

the number of the image within the sequence. If the sequence is animating, this will be the number of the image displayed at the time the animation was initiated.

Icon Information

If the option *display Icon information* is turned on, then sequence information will be displayed on every Icon Image (each of which represents a DICOM sequence) in the DICOM Icon Preview .

This consists of patient Information:

Name,

ID number. sex.

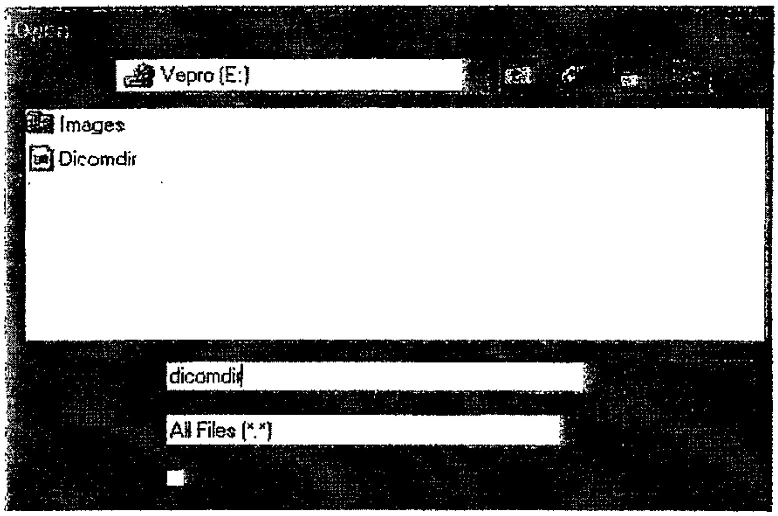
and Information about the sequence/image:

recording method. recording date, recording time and

filename.

DICOM CD's

CDs which confirm to the DICOM 3.0 standard have a file in the main directory (root directory) named DICOMDIR. In this file are references to the pictures and picture sequences available on the CD. Representative icons and information for these icons are also enclosed within this file for every sequence on the disk. This list of icons enables us to display an Icon Preview or a DICOM File Selection Dialog Box making it much easier for you to select the correct sequence for viewing.



Changing the Global Palette in 256 Color Mode

If Windows is set to use 256 colors as its display mode, this may mean that the Viewing Software will run faster, however it also means that Viewing Software is limited (by Windows) to 256 colors too! To avoid nasty flickering when switching between color and grayscale pictures, and to optimize performance, the Viewing Software uses a fixed color palette in this graphic mode.

The fixed color palette may be changed by the user from a **grayscale palette** with 256 shades of gray, to a **multicolor palette** with a wide variety of colors. The grayscale palette is best for viewing images that compose of shades of gray, such as most Cardiology images (and most medical images). The multicolor palette is best for viewing photographs and most non-medical color images. The multicolor palette can display a maximum of 16 shades of gray (in addition to the rainbow colors), so normal Cardiology images with 256 shades of gray will appear quite ragged.

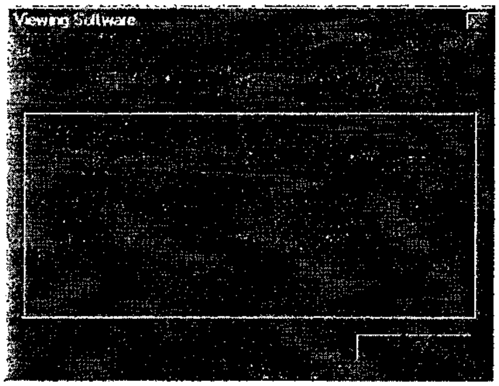
Note: For predominantly gray medical images we recommend using the (default) grayscale palette, as it shows the images much more accurately.

You can toggle between the two palettes by clicking on the button on the Standard Toolbar. When this button is in its normal state (as the picture shows), then the default grayscale palette is used for displaying the images. When this button is pressed in, then it is using the multicolor palette.

The Video Speed Test

As a general animation performance indicator, you may choose to run a Video Speed Test at application startup. This test measures how many frames your computer can display per second before frame-dropping is necessary. (See also: Options „Skip Frames to Maintain speed").

After the speed test is complete, if your computer is judged not to be able to reach 25 frames per second with standard (512 x 512) cardio images, the speed test will report how many frames-per-second your computer can hope to achieve, under the current graphic mode.



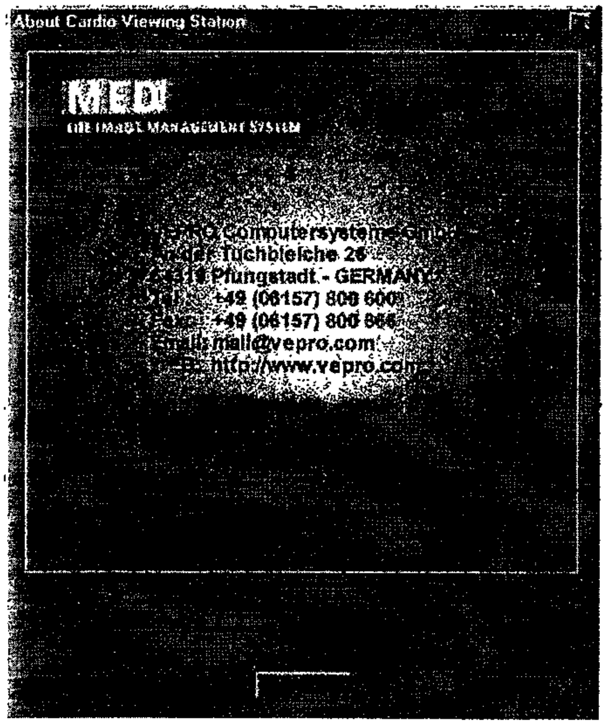
This test may be useful to find out under which graphics mode your computer runs fastest. For example, many computers run 2x faster running Windows with 256 colors as compared to the 24-bit (16.8 million colors) mode.

You may turn this start-up option on or off by clicking on the *View* menu option *Video Speed Test at Startup* (See: Menus - A ticked entry means this option is turned on, and will appear every time at application startup.

Support

System Support

For service call your technical support and give them your System-ID which can be found in the pull down-menu „Help - About..."



APPENDIX: DICOM Conformance Statement

DICOM Conformance Statement

ACOM.Convert

Version 4.42

Document Version: 1.0

08. May 1999

Media Storage Conformance Statement

Introduction

The application described in this conformance statement (*ACOM.Convert*) provides standard DICOM interchange on CD-R to support the cine replacement standard. It also provides an implementation of a powerful Viewing Station for DICOM and other medical image data.

The application is designed to write previously acquired image sequences as different IOD's as defined in the DICOM standard to CD-R exchange media and read different IODs such as e.g. CT, MR and X-ray Angiographic defined in the DICOM standard.

The implementation claims DICOM Media Interchange conformance in accordance to the NEMA standard PS3.2.

Implementation Model

The *Media Creator* generates a DICOM File Set of various DICOM SOP instances and writes this File Set to 120mm Compact Disc Recordable (CD-R) according to the specified Application Profiles.

The *Image Reader* reads a variety of DICOM SOP instances from several media like 120mm Compact Disc Recordable (CD-R) and PC File Systems according to the specified Application Profiles.

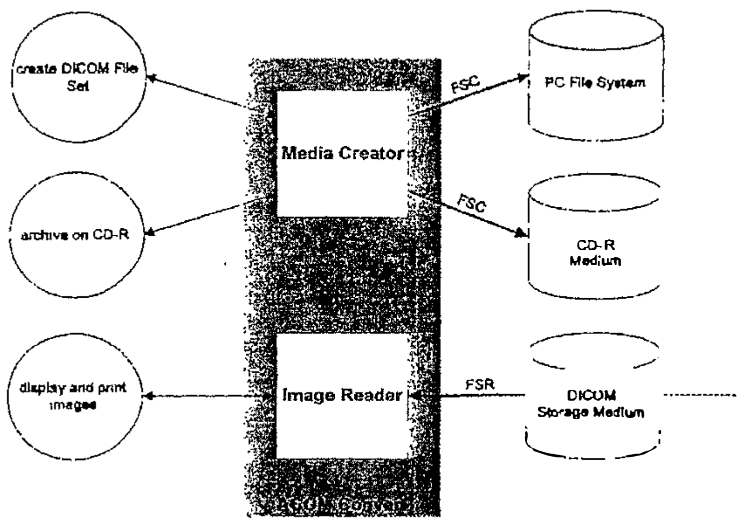
Application Data Flow Diagram

The Media Storage part of the *ACOM.Convert* application can be represented by two different Application Entities:

- The *Media Creator* describes the creation of a DICOM file set and writing this file set to a blank CD-R media.
- The *Image Reader* describes a reading process. Initiated by the operator, the *Image Reader* can read a variety of SOP Instances stored on one of several different media types for the purpose of viewing, image processing and printing.

Figure 1.2.1 shows the Application Data Flow Diagram.

Figure 1.2.1: the Application Data Flow Diagram



Functional definitions of Application Entities

Media Creator

The AE "*Media Creator*" supports the following functions:

- Creation of a DICOM File Set.
- Write DICOM File Set to CD-R.

Image Reader

The AE "*Image Reader*" supports the following functions:

- Read the DICOMDIR file that represents the contents of the data as recorded. This information can be displayed as a set of icons annotated or not annotated by identifying information such as patient name, etc. or as a table listing the identifying information.
- Read a selected SOP Instance from several different devices for the purpose of displaying, image processing and printing.

Sequencing of Real World Activities

Media Creator

Create DICOM File Set:

After the receiving SOP instances over the Network, these SOP instances are automatically stored on a PC File System.

Archive on CD-R:

After inserting a blank CD-R the user has to select several SOP Instances from a study list. From these studies a new DICOM File set is created and written to the CD-R.

Image Reader

Display directory:

After inserting a CD-R disc whose data conform to one of the supported application profiles the operator has to press a button to view the contents of the DICOMDIR file.

Display and process images:

The operator has to select a SOP instance from one of the supported media types or select an image from the contents of the DICOMDIR file to view and process images.

Print images:

After selecting a SOP instance for display the operator has to press a button to print the selected image on a standard paper printer.

File Meta Information

The *ACOM.Convert* provides the following File Meta Information :

- File Meta Information Version is set to 1
- ImplementationClassUID is set to "1.2.276.0.19.1996.1"
- ImplementationVersionName is set to "4.31 "
- SourceApplicationEntityTitle is set to "MEDImage"

Application Entity Specifications

AE Specification: Media Creator

The *Media Creator* provides standard conformance to DICOM Interchange Option of the Media Storage Service Class (PS 3.4). The Application Profiles, roles and options are listed in Table 1.3.1.

Table 1.3.1: Application Profiles, Activities and Roles of the CRS Media Creator

Application Profiles Supported	Real World Activity	Role	SC Option
STD-XABC-CD	Archive on CDR	FSC	Interchange
STD-GEN-CD	Archive on CDR	FSC	Interchange
PRI-WRITE-FILE	Create DICOM File Set	FSC	Interchange

Real-World Activities

Archive on CD-R

The *Media Creator* will act as a FSC using Interchange Option when writing a DICOM File Set to a CD-R.

Create DICOM File Set

The *Media Creator* will act as a FSC using Interchange Option when writing a DICOM File Set to a PC File System.

Application Profile

Refer to Table 1.3.1 for identifying and chapter 1.4 for the definition of the Application Profiles that invoke this AE.

AE Specification: Image Reader

The *Image Reader* provides standard conformance to DICOM Interchange Option of the Media Storage Service Class (PS 3.4). The Application Profiles, roles and options are listed in Table 1.3.2.

Table 1.3.2: Application Profiles, Activities and Roles of the CRS Image Reader

Application Profiles Supported	Real World Activity	Role	SC Option
STD-XABC-CD	Display Directory Display and process Images	FSR	Interchange
STD-GEN-CD	Display Directory Display and Print Images	FSR	Interchange
PRI-READ-FILE	Display and Print Images	FSR	Interchange

Real-World Activities

Display Directory

The *Image Reader* will act as a FSR using Interchange Option when reading the DICOMDIR file of the medium.

Display and Process Images

The *Image Reader* will act as a FSR using Interchange Option when reading the requested images.

Application Profile

Refer to Table 1.3.2 for identifying and chapter 1.4 for the definition of the Application Profiles that invoke this AE.

Private Application Profiles

Private Application Profile: Media Creator

Class and Profile Identification

This chapter defines an Application Profile Class for the *ACOMConvert* and several Application Profiles defined within this class. The only difference between these profiles is the choice of media. Table 1.3.1 lists the defined Application Profiles and its identifiers.

Table 1.4.1: Application Profiles defined within this Application Profile Class

Application Profiles Supported	Identifier	Description
Private Image Interchange for PC File System	PRI-WRITE-FILE	writes DICOM SOP instances to PC File System

Clinical Context

This class of Application Profiles provides a multimedia data interchange facility for a wide area of different clinical environments.

Roles and Service Class Options

All Application Profiles defined within this Application Profile Class use the Media Storage Service Class defined in PS3.4 with the Interchange Option. The *Media Creator* acts as a File Set Creator (FSC) as defined in PS 3.10.

General Class Profile

This section defines common characteristics of all Application Profiles defined within this Application Profile Class.

SOP Classes and Transfer Syntax's

Table 1.4.2 lists the SOP Classes and corresponding Transfer Syntax's common for all Application Profiles in this class. Table 1.3.1 lists the corresponding roles and options.

Table 1.4.2: SOP Classes and Transfer Syntax's

SOP Class	SOP Class UID	Transfer Syntax Definition	Transfer Syntax UID
Basic Directory	1 2 840 10008.1 3.10	Explicit VR Little Endian	1.2.840.10008.1.2.1
Computed Radiography Image Storage	1.2.840 10008 5.1 4.1.1 1	Explicit VR Little Endian	1 2 840.10008 1 2 1
		Lossy JPEG Explicit VR Little Endian	1 2.840.10008.1.2 4.50
		Lossless JPEG Explicit VR Little Endian	1.2 840.10008.1.2.4.70
Digital X-Ray Image Storage - For Presentation	1 2 840 10008.5 1.4.1.1.1 1	Explicit VR Little Endian	1.2.840.10008 1.2 1
		Lossy JPEG Explicit VR Little Endian	1 2 840 10008.1 2 4 50
		Lossless JPEG Explicit VR Little Endian	1 2 840.10008.1 2 4.70
Digital X-Ray Image Storage - For Processing	1 2 840.10008 5.1 4 1 1 1.1 1	Explicit VR Little Endian	1 2.840.10008.1 2.1
		Lossy JPEG Explicit VR Little Endian	1 2.840.10008.1.2.4 50
		Lossless JPEG Explicit VR Little Endian	1 2.840 10008.1 2.4.70
Digital Mammography X-Ray Image Storage - For Presentation	1.2 840 10008 5 1 4.1 1 1 2	Explicit VR Little Endian	1 2.840.10008.1 2.1
		Lossy JPEG Explicit VR Little Endian	1 2 840 10008.1 2.4 50
		Lossless JPEG Explicit VR Little Endian	1 2 840 10008 1 2.4.70
Digital Mammography X-Ray Image Storage - For Processing	1 2 840 10008.5 1 4.1.1 1 2.1	Explicit VR Little Endian	1 2 840.10008.1 2.1
		Lossy JPEG Explicit VR Little Endian	1 2.840 10008.1 2.4 50
		Lossless JPEG Explicit VR Little Endian	1.2.840.10008.1 2.4.70
CT Image Storage	1 2.840.10008 5.1.4.1.1.2	Explicit VR Little Endian	1 2.840.10008.1.2.1
		Lossy JPEG Explicit VR Little Endian	1.2.840.10008.1 2 4 50
		Lossless JPEG Explicit VR Little Endian	1.2.840.10008.1 2 4.70
Ultrasound Multi-frame Image Storage (Retired)	*1 2 840.10008 5.1 4 1 1 3*	Explicit VR Little Endian	1 2.840 10008.1 2.1
		Lossy JPEG Explicit VR Little Endian	1.2.840.10008.1.2 4.50
		Lossless JPEG Explicit VR Little Endian	1 2 840.10008.1 2 4.70
Ultrasound Multi-frame Image Storage	1 2 840.10008 5 1.4 1.1 3.1	Explicit VR Little Endian	1 2 840 10008 1 2.1
		Lossy JPEG Explicit VR Little Endian	1 2 840.10008 1 2.4.50
		Lossless JPEG Explicit VR Little Endian	1.2 840 10008 1 2.4.70
MR Image Storage	1 2 840 10008 5.1 4.1 1 4	Explicit VR Little Endian	1 2 840.10008.1.2.1
		Lossy JPEG Explicit VR Little Endian	1 2.840 10008.1 2 4.50
		Lossless JPEG Explicit VR Little Endian	1.2.840.10008.1 2 4.70
Nuclear Medicine Image Storage (Retired)	*1.2.840.10008 5.1 4.1.1 5*	Explicit VR Little Endian	1.2.840.10008.1 2.1
		Lossy JPEG Explicit VR Little Endian	1.2.840.10008.1 50
		Lossless JPEG Explicit VR Little Endian	1.2.840.10008.1 70

Ultrasound Image Storage (Retired)	*1 2.840 10008.5 1 4 1 1.6*	Explicit VR Little Endian	1 2.840.10008.1.2.1
		Lossy JPEG Explicit VR Little Endian	1 2.840.10008.1 2.4 50
		Lossless JPEG Explicit VR Little Endian	1 2 840.10008.1 2.4.70
Ultrasound Image Storage	1.2.840.10008 5 1 4.1.1 6.1	Explicit VR Little Endian	1.2 840.10008 1 2.1
		Lossy JPEG Explicit VR Little Endian	1 2.840.10008.1 2.4.50
		Lossless JPEG Explicit VR Little Endian	1 2.840 10008 1.2.4.70
Secondary Capture Image Storage	1.2.840 10008.5.1.4.1 1.7	Explicit VR Little Endian	1.2 840.10008.1 2.1
		Lossy JPEG Explicit VR Little Endian	1 2 840.10008 1.2.4.50
		Lossless JPEG Explicit VR Little Endian	1 2 840 10008.1 2.4.70
X-Ray Angiographic Image Storage	1.2.840.10008.5.1.4.1.1.12.1	Explicit VR Little Endian	1.2.840 10008.1 2.1
		Lossy JPEG Explicit VR Little Endian	1 2.840.10008 1 2.4.50
		Lossless JPEG Explicit VR Little Endian	1 2 840 10008.1 2.4.70
X-Ray Radiofluoroscopic Image Storage	1.2.840.10008.5.1.4.1.1.12.2	Explicit VR Little Endian	1.2.840.10008.1.2 1
		Lossy JPEG Explicit VR Little Endian	1.2 840.10008.1.2.4 50
		Lossless JPEG Explicit VR Little Endian	1 2 840 10008.1 .2.4 70
Nuclear Medicine Image Storage	1 2.840.10008.5.1.4.1.1.20	Explicit VR Little Endian	1.2.840.10008.1 2.1
		Lossy JPEG Explicit VR Little Endian	1 2 840.10008.1 2.4.50
		Lossless JPEG Explicit VR Little Endian	1 2.840.10008.1.2.4.70

Physical Medium and Media Format

There are no common physical media to all defined Application Profiles.

Directory Information in DICOMDIR

There is no information additional to the Directory IOD.

Specific Application Profiles

This section describes the different media supported by the *Media Creator* as specific characteristics to the different Application Profiles.

PRI-WRITE-FILE Profile

This Application Profile is private in the sense of PS 3.2. The only specific characteristic to the defined Application Profile Class is the support for PC File Systems as specified in PS 3.12.

Private Application Profile: Image Reader

Class and Profile Identification

This chapter defines an Application Profile Class for the *Image Reader* and several Application Profiles defined within this class. The only difference between these profiles is the choice of media. Table 1.4.3 lists the defined Application Profiles and its identifiers.

Table 1.4.3: Application Profiles defined within this Application Profile Class

Application Profiles Supported	Identifier	Description
Private Image Interchange for PC File System	PRI-READ-FILE	Reads a variety of DICOM SOP instances from PC File System

Clinical Context

This class of Application Profiles provides a multimedia data interchange facility for a wide area of different clinical environments. Furthermore, several different modalities such as e.g. CT, MR and XA supported by the application, enhance it to a multi-modality-system.

Roles and Service Class Options

All Application Profiles defined within this Application Profile Class use the Media Storage Service Class defined in PS3.4 with the Interchange Option. The *Image Reader* act as a File Set Reader (FSR) as defined in PS 3.10.

General Class Profile

This section defines common characteristics of all Application Profiles defined within this Application Profile Class.

SOP Classes and TransferSyntax's

Table 1.4.4 lists the SOP Classes and corresponding Transfer Syntax's common for all Application Profiles in this class. Table 1.3.2 lists the corresponding roles and options

Table 1.4.4: SOP Classes and Transfer Syntax's

SOP Class	SOP Class UID	Transfer Syntax Definition	Transfer Syntax UID
Basic Directory	1.2.840.10008.1.3.10	Explicit VR Little Endian	1.2.840.10008.1.2.1
Computed Radiography Image Storage	1.2.840.10008.5.1.4.1.1.1	Implicit VR Little Endian	1.2.840.10008.1.2
		Explicit VR Little Endian	1.2.840.10008.1.2.1
		Explicit VR Big Endian	1.2.840.10008.1.2.2
		Lossy JPEG Explicit VR Little Endian	1.2.840.10008.1.2.4.50
		Lossless JPEG Explicit VR Little Endian	1.2.840.10008.1.2.4.70
Digital X-Ray Image Storage - For Presentation	1.2.840.10008.5.1.4.1.1.1.1	Implicit VR Little Endian	1.2.840.10008.1.2
		Explicit VR Little Endian	1.2.840.10008.1.2.1
		Explicit VR Big Endian	1.2.840.10008.1.2.2
		Lossy JPEG Explicit VR Little Endian	1.2.840.10008.1.2.4.50
		Lossless JPEG Explicit VR Little Endian	1.2.840.10008.1.2.4.70
Digital X-Ray Image Storage - For Processing	1.2.840.10008.5.1.4.1.1.1.1.1	Implicit VR Little Endian	1.2.840.10008.1.2
		Explicit VR Little Endian	1.2.840.10008.1.2.1
		Explicit VR Big Endian	1.2.840.10008.1.2.2
		Lossy JPEG Explicit VR Little Endian	1.2.840.10008.1.2.4.50
		Lossless JPEG Explicit VR Little Endian	1.2.840.10008.1.2.4.70

Digital Mammography X-Ray Image Storage - For Presentation	1.2.840.10008.5.1.4.1.1.1.2	Implicit VR Little Endian	1.2.840.10008.1.2
		Explicit VR Little Endian	1.2.840.10008.1.2.1
		Explicit VR Big Endian	1.2.040.10008.1.2.2
		Lossy JPEG Explicit VR Little Endian	1.2.840.10008.1.2.4.50
		Lossless JPEG Explicit VR Little Endian	1.2.840.10008.1.2.4.70
Digital Mammography X-Ray Image Storage – For Processing	1.2.840.10008.5.1.4.1.1.1.2.1	Implicit VR Little Endian	1.2.840.10008.1.2
		Explicit VR Little Endian	1.2.840.10008.1.2.1
		Explicit VR Big Endian	1.2.840.10008.1.2.2
		Lossy JPEG Explicit VR Little Endian	1.2.840.10008.1.2.4.50
		Lossless JPEG Explicit VR Little Endian	1.2.840.10008.1.2.4.70
CT Image Storage	1.2.840.10008.5.1.4.1.1.2	Implicit VR Little Endian	1.2.840.10008.1.2
		Explicit VR Little Endian	1.2.840.10008.1.2.1
		Explicit VR Big Endian	1.2.840.10008.1.2.2
		Lossy JPEG Explicit VR Little Endian	1.2.840.10008.1.2.4.50
		Lossless JPEG Explicit VR Little Endian	1.2.840.10008.1.2.4.70
Ultrasound Multi frame Image Storage (Retired)	*1.2.840.10008.5.1.4.1.1.3*	Implicit VR Little Endian	1.2.840.10008.1.2
		Explicit VR Little Endian	1.2.840.10008.1.2.1
		Explicit VR Big Endian	1.2.840.10008.1.2.2
		Lossy JPEG Explicit VR Little Endian	1.2.840.10008.1.2.4.50
		Lossless JPEG Explicit VR Little Endian	1.2.840.10008.1.2.4.70
		Lossless RLE	1.2.840.10008.1.2.5
Ultrasound Multi-frame Image Storage	1.2.840.10008.5.1.4.1.1.3.1	Implicit VR Little Endian	1.2.840.10008.1.2
		Explicit VR Little Endian	1.2.840.10008.1.2.1
		Explicit VR Big Endian	1.2.840.10008.1.2.2
		Lossy JPEG Explicit VR Little Endian	1.2.840.10008.1.2.4.50
		Lossless JPEG Explicit VR Little Endian	1.2.840.10008.1.2.4.70
		Lossless RLE	1.2.840.10008.1.2.5
MR Image Storage	1.2.840.10008.5.1.4.1.1.4	Implicit VR Little Endian	1.2.840.10008.1.2
		Explicit VR Little Endian	1.2.840.10008.1.2.1
		Explicit VR Big Endian	1.2.840.10008.1.2.2
		Lossy JPEG Explicit VR Little Endian	1.2.840.10008.1.2.4.50
		Lossless JPEG Explicit VR Little Endian	1.2.840.10008.1.2.4.70
Nuclear Medicine Image Storage (Retired)	*1.2.840.10008.5.1.4.1.1.5*	Implicit VR Little Endian	1.2.840.10008.1.2
		Explicit VR Little Endian	1.2.840.10008.1.2.1
		Explicit VR Big Endian	1.2.840.10008.1.2.2
		Lossy JPEG Explicit VR Little Endian	1.2.840.10008.1.2.4.50
		Lossless JPEG Explicit VR Little Endian	1.2.840.10008.1.2.4.70
Ultrasound Image Storage (Retired)	*1.2.840.10008.5.1.4.1.1.6*	Implicit VR Little Endian	1.2.840.10008.1.2
		Explicit VR Little Endian	1.2.840.10008.1.2.1
		Explicit VR Big Endian	1.2.840.10008.1.2.2
		Lossy JPEG Explicit VR Little Endian	1.2.840.10008.1.2.4.50
		Lossless JPEG Explicit VR Little Endian	1.2.840.10008.1.2.4.70
		Lossless RLE	1.2.840.10008.1.2.5

Ultrasound Image Storage	1 2.840 10008 5.1 4.1.1 6 1	Implicit VR Little Endian	1 2 840.10008.1 2
		Explicit VR Little Endian	1.2.840.10008.1.2.1
		Explicit VR Big Endian	1.2.840.10008.1.2 2
		Lossy JPEG Explicit VR Little Endian	1 2.840.10008.1.2.4.50
		Lossless JPEG Explicit VR Little Endian	1.2.840.10008.1.2.4.70
		Lossless RLE	1.2.840 10008.1 2.5
Secondary Capture Image Storage	1.2.840 10008.5 1.4.1 1 7	Implicit VR Little Endian	1 2 840.10008.1 2
		Explicit VR Little Endian	1 2.840.10008.1.2.1
		Explicit VR Big Endian	1.2.840.10008.1 2 2
		Lossy JPEG Explicit VR Little Endian	1 2 840 10008.1 2.4.50
		Lossless JPEG Explicit VR Little Endian	1 2.840.10008.1.2.4.70
X-Ray Angiographic Image Storage	1 2 840 10008 5.1 4 1.1.12 1	Implicit VR Little Endian	1.2.840.10008.1 2
		Explicit VR Little Endian	1 2.840.10008.1.2.1
		Explicit VR Big Endian	1 2 840.10008.1 2.2
		Lossy JPEG Explicit VR Little Endian	1 2 840.10008.1.50
		Lossless JPEG Explicit VR Little Endian	1 2.840.10008.1.70
X-Ray Radiofluoroscopic Image Storage	1.2.840.10008 5.1.4.1.1 12 2	Implicit VR Little Endian	1 2.840.10008.1.2
		Explicit VR Little Endian	1.2.840.10008.1.2.1
		Explicit VR Big Endian	1 2 840.10008.1 2 2
		Lossy JPEG Explicit VR Little Endian	1 2 840.10008.1.2.4.50
		Lossless JPEG Explicit VR Little Endian	1 2.840.10008.1 2.4.70
Nuclear Medicine Image Storage	1 2 840.10008.5 1 4.1.1 20	Implicit VR Little Endian	1.2 840.10008.1.2
		Explicit VR Little Endian	1 2.840.10008.1 2.1
		Explicit VR Big Endian	1.2 840.10008.1 2.2
		Lossy JPEG Explicit VR Little Endian	1.2.840.10008 1 50
		Lossless JPEG Explicit VR Little Endian	1 2 840.10008.1.70

Physical Medium and Media Format

There are no common physical media to all defined Application Profiles.

Directory Information in DICOMDIR

There are no additional to the Directory IOD.

Specific Application Profiles

This section describes the different media supported by the *Image Reader* as specific characteristics to the different Application Profiles.

PRI-READ-FILE Profile

This Application Profile is private in the sense of PS 3 2. The only specific characteristic to the defined Application Profile Class is the support for PC File Systems as specified in PS 3.12.

Network Conformance Statement

Introduction

The application described in this conformance statement (*ACOM.Convert*) allows the transfer of images between this application and other DICOM Application Entities (AEs). This application acts as a service class user (SCU) and as a service class provider for both Storage Service Class and Verification Service Class.

Implementation Model

The *ACOM.Convert* is implemented to support one DICOM Application Entity that receives associations from remote Application Entities.

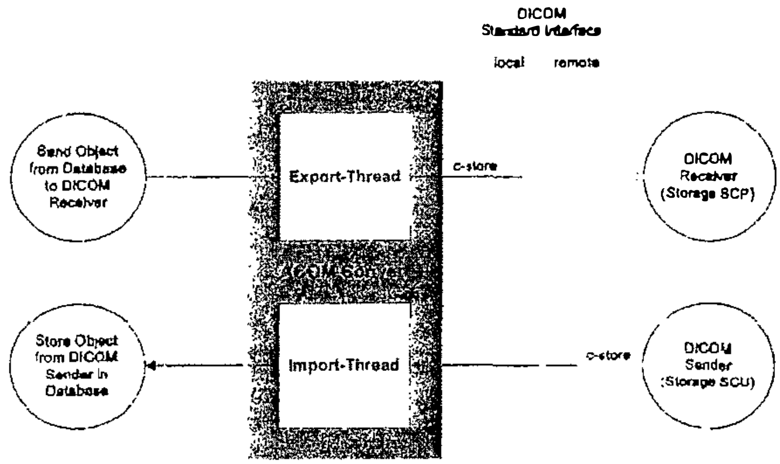
The *ACOM.Convert* originates associations for Storage of DICOM Composite Information Objects in remote Application Entities.

Application Data Flow Diagram

The ACOM.Convert main interface forks child threads for exporting images (*Export Thread*) and importing images (*Import Thread*) using the DICOM Storage service class..

The *Export Thread* initiates associations for DICOM Storage Service Class to remote AEs. For each image that should be sent, the image is read, converted to a DICOM Information Object (DIO), a new association to the remote DICOM AE is initiated and then the DIO is sent. After sending the association is closed.

A remote Application Entity initiates an association for DICOM Storage Service Class to AE of the *Import Thread* Upon acceptance of the association by *Import Thread*, the remote AE transmits the DICOM Information Objects (DIOs). Every DIO is received and stored on the local hard-disk



Functional definitions of Application Entities

The *Export Thread* acting as an SCU automatically sends a set of selected SOP instances to a specific remote AE. Upon such a request, it initiates an association with the remote AE and transfers the data. The Application Entity Title, the IP-Address and the Port Number to which the SCU is sending are taken from a local configuration file.

The *Import Thread* acting as a SCP waits for association requests from a any remote DICOM client to receive a DIO. The Port Number to which the SCP is listening on are taken from a local configuration file.

Sequencing of Real World Activities

Send Object

The Operator selects SOP instances from one or more patients. After the selection is complete, each selected SOP instance is sent automatically to a specific remote AE.

Application Entity Specifications

Export Thread Specification

The Export Thread provides standard Conformance to the DICOM V3.0 SOP Classes listed in table 2.3.1 as an SCU:

Table 2.3.1: SOP Classes as an SCU

SOP CLASS NAME	SOP CLASS UID
Verification	1.2.840.10008.1.1
Computed Radiography Image Storage	1.2.840.10008.5.1.4.1.1.1
Digital X-Ray Image Storage – For Presentation	1.2.840.10008.5.1.4.1.1.1.1
Digital X-Ray Image Storage – For Processing	1.2.840.10008.5.1.4.1.1.1.1.1
Digital Mammography X-Ray Image Storage - For Presentation	1.2.840 10008.5.1 4.1.1.1.2
Digital Mammography X-Ray Image Storage - For Processing	1.2.840.10008.5.1.4.1.1.1.2.1
CT Image Storage	1.2.840.10008.5.1.4.1.1.2
Ultrasound Multi-frame Image Storage (Retired)	*1.2.840.10008.5.1.4.1 1.3*
Ultrasound Multi-frame Image Storage	1.2.840.10008.5.1.4.1.1.3.1
Nuclear Medicine Image Storage (Retired)	*1.2 840.10008.5 1.4.1.1.5*
Ultrasound Image Storage (Retired)	*1.2 840.10008.5.1.4.1.1 6*
Ultrasound Image Storage	1.2 840.10008.5.1.4.1.1.6.1
Secondary Capture Image Storage	1 2 840.10008.5.1.4.1.1.7
X-Ray Angiographic Image Storage	1.2.840.10008.5.1.4.1.1.12.1
X-Ray Radiofluoroscopic Image Storage	1.2.840.10008.5.1.4.1.1.12.2
Nuclear Medicine Image Storage	1.2.840.10008.5 1.4.1.1.20

Association Establishment Policies

General

The Application Entity Title, the port number and the TCP/IP address of the remote Application Entity are defined in the configuration file of the *ACOM.Convert*.

Number of Associations

The *Export Thread* initiates only one association at a time.

Asynchronous Nature

This version of the *ACOM.Convert* does not support asynchronous communication.

Implementation Identifying Information

The *ACOM.Convert* provides the following Implementation Identifying Information :

- Default AE Title is set to "VTSERVER"
- ImplementationClassUID is set to "1.2.276.0.19.1996.1"
- ImplementationVersionName is set to "4.31 "
- SourceApplicationEntityTitle is set to "MEDImage"

Association Initiation Policy

DIS attempts to initiate a new association for each SOP Instance it attempts to transfer.

Send Echo

Associated Real World Activity

The associated Real-World activity is a C-Echo request initiated by the *ACOM.Convert*. The user has to press the "Send DICOM Echo" button for testing the connection to the configured remote host.

Proposed Presentation Contexts

The *ACOM.Convert* will propose Presentation Contexts as shown in the following table:

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Extended
Name	UID	Name List	UID List		Negotiation
Verification	1 2 840.10008.1.1	Implicit VR Little Endian	1 2 840 10008 1 2	SCU	none

Send Image to a Remote Node

Associated Real World Activity

The associated Real-World activity is a C-Store request initiated by the *Export Thread* after the user has selected SOP Instances from one or more patient for network transfer. The *Export Thread* reads the image, converts it if necessary, initiates an association, sends it to the remote host, closes the association and deletes the sent image.

If the C-Store Response from the remote Application contains a status other than Success, the association is aborted. After a configurable time period, the transfer is started again. This happens until the C-Store succeeds or an configurable number of tries are reached. Then the image is moved to a 'bad' folder and a comment is written to a log file.

Proposed Presentation Contexts

The *Export Thread* will propose Presentation Contexts as shown in the following table:

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Extended
Name	UID	Name List	UID List		Negotiat.
Computed Radiography Image Storage	1.2.840 10008.5 1.4.1.1.1	Implicit VR Little Endian	1 2.840.10008.1 2	SCU	none
		Explicit VR Little Endian	1 2.840 10008 1 2.1		
Digital X-Ray Image Storage – For Presentation	1 2.840.10008 5.1.4.1 1 1 1	Implicit VR Little Endian	1 2 840.10008 1 2	SCU	none
		Explicit VR Little Endian	1.2.840.10008 1 2.1		
Digital X-Ray Image Storage– For Processing	1 2 840.10008 5.1 4.1.1 1.1.1	Implicit VR Little Endian	1.2 840.10008 1.2	SCU	none
		Explicit VR Little Endian	1 2.840.10008 1 2.1		
Digital Mammography X-Ray Image Storage - For Presentation	1.2 840.10008.5 1 4 1 1.1.2	Implicit VR Little Endian	1.2 840.10008.1 2	SCU	none
		Explicit VR Little Endian	1.2.840 10008.1 2.1		
Digital Mammography X-Ray Image Storage - For Processing	1 2.840.10008.5.1 4.1 1 1.2.1	Implicit VR Little Endian	1 2 840 10008.1.2	SCU	none
		Explicit VR Little Endian	1.2.840.10008.1 2.1		
CT Image Storage	1.2.840.10008.5.1.4.1.1 2	Implicit VR Little Endian	1.2.840.10008.1.2	SCU	none
		Explicit VR Little Endian	1.2 840.10008.1 2 1		

Ultrasound Multi frame Image Storage (Retired)	*1.2.840.10008.5.1.4.1.1.3*	Implicit VR Little Endian Explicit VR Little Endian	1.2.840.10008.1.2 1.2.840.10008.1.2.1	SCU	none
Ultrasound Multi-frame Image Storage	1.2.840.10008.5.1.4.1.1.3.1	Implicit VR Little Endian Explicit VR Little Endian	1.2.840.10008.1.2 1.2.840.10008.1.2.1	SCU	None
MR Image Storage	1.2.840.10008.5.1.4.1.1.4	Implicit VR Little Endian Explicit VR Little Endian	1.2.840.10008.1.2 1.2.840.10008.1.2.1	SCU	None
Nuclear Medicine Image Storage (Retired)	*1.2.840.10008.5.1.4.1.1.5*	Implicit VR Little Endian Explicit VR Little Endian	1.2.840.10008.1.2 1.2.840.10008.1.2.1	SCU	None
Ultrasound Image Storage (Retired)	*1.2.840.10008.5.1.4.1.1.6*	Implicit VR Little Endian Explicit VR Little Endian	1.2.840.10008.1.2 1.2.840.10008.1.2.1	SCU	None
Ultrasound Image Storage	1.2.840.10008.5.1.4.1.1.6.1	Implicit VR Little Endian Explicit VR Little Endian	1.2.840.10008.1.2 1.2.840.10008.1.2.1	SCU	None
Secondary Capture Image Storage	1.2.840.10008.5.1.4.1.1.7	Implicit VR Little Endian Explicit VR Little Endian	1.2.840.10008.1.2 1.2.840.10008.1.2.1	SCU	None
X-Ray Angiographic Image Storage	1.2.840.10008.5.1.4.1.1.12.1	Implicit VR Little Endian Explicit VR Little Endian Lossless JPEG Explicit VR Little Endian	1.2.840.10008.1.2 1.2.840.10008.1.2.1 1.2.840.10008.1.2.4.70	SCU	None
X-Ray Radiofluoroscopic Image Storage	1.2.840.10008.5.1.4.1.1.12.2	Implicit VR Little Endian Explicit VR Little Endian Lossless JPEG Explicit VR Little Endian	1.2.840.10008.1.2 1.2.840.10008.1.2.1 1.2.840.10008.1.2.4.70	SCU	None
Nuclear Medicine Image Storage	1.2.840.10008.5.1.4.1.1.20	Implicit VR Little Endian Explicit VR Little Endian	1.2.840.10008.1.2 1.2.840.10008.1.2.1	SCU	none

SOP Specific Conformance Statement to Storage SOP classes

The DICOM objects created by this application conform to the standard DICOM IOD definitions, but they may contain additional private elements which should be ignored by a DICOM receiver.

Import Thread Specification

The Import Thread provides standard Conformance to the DICOM V3.0 SOP Classes listed in table 2.3.2 as an SCU:

Table 2.3.2: SOP Classes as an SCP

SOP CLASS NAME	SOP CLASS UID
Verification	1.2.840.10008.1.1
Computed Radiography Image Storage	1.2.840.10008.5.1.4.1.1.1
Digital X-Ray Image Storage - For Presentation	1.2.840.10008.5.1.4.1.1.1.1
Digital X-Ray Image Storage – For Processing	1.2.840.10008.5.1.4.1.1.1.1.1
Digital Mammography X-Ray Image Storage - For Presentation	1.2.840.10008.5.1.4.1.1.1.2
Digital Mammography X-Ray Image Storage - For Processing	1.2.840.10008.5.1.4.1.1.1.2.1
CT Image Storage	1.2.840.10008.5.1.4.1.1.2
Ultrasound Multi-frame Image Storage (Retired)	*1.2.840.10008.5.1.4.1.1.3*
Ultrasound Multi-frame Image Storage	1.2.840.10008.5.1.4.1.1.3.1
Nuclear Medicine Image Storage (Retired)	*1.2.840.10008.5.1.4.1.1.5*
Ultrasound Image Storage (Retired)	*1.2.840.10008.5.1.4.1.1.6*
Ultrasound Image Storage	1.2.840.10008.5.1.4.1.1.6.1
Secondary Capture Image Storage	1.2.840.10008.5.1.4.1.1.7
X-Ray Angiographic Image Storage	1.2.840.10008.5.1.4.1.1.12.1
X-Ray Radiofluoroscopic Image Storage	1.2.840.10008.5.1.4.1.1.12.2
Nuclear Medicine Image Storage	1.2.840.10008.5.1.4.1.1.20

Association Establishment Policies

General

The Port Number to which the SCP is listening on can be configured in a local configuration file of the *ACOM.Convert*.

Number of Associations

The *Import Thread* accepts only one association at a time.

Asynchronous Nature

This version of the *ACOM.Convert* does not support asynchronous communication.

Implementation Identifying Information

The *ACOM.Convert* provides the following Implementation Identifying Information :

- Default AE Title is set to "VTSERVER"
- ImplementationClassUID is set to "1.2.276.0.19.1996.1"
- ImplementationVersionName is set to "4.31 "
- SourceApplicationEntityTitle is set to "MEDImage"

Association Acceptance Policy

When the *Import Thread* accepts an association, it will receive any images transmitted on that association and store the images on the harddisk. The format used for storage is described in the media storage part of this conformance statement. The *Import Thread* makes no limitations on who may connect.

Receive Echo

Associated Real World Activity

The associated Real-World activity is a C-Echo response by the *Import Thread*.

Proposed Presentation Context

The *ACOM.Convert* will propose Presentation Contexts as shown in the following table:

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Extended
Name	UID	Name List	UID List		Negotiation
Verification	1.2.840.10008.1.1	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	none

Receive Image from a Remote Node

Associated Real-World Activity

The associated Real-World activity is a C-Store request received by the *Import Thread*. After accepting an association from a remote DICOM AE the *Import Thread* receives the image, stores it on the local hard-disk.

Proposed Presentation Contexts

The *Import Thread* will propose Presentation Contexts as shown in the following table:

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Extended
Name	UID	Name List	UID List		Negotiat.
Computed Radiography Image Storage	1.2.840.10008.5.1.4.1.1.1	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	none
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
Digital X-Ray Image Storage – For Presentation	1.2.840.10008.5.1.4.1.1.1.1	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	none
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
Digital X-Ray Image Storage – For Processing	1.2.840.10008.5.1.4.1.1.1.1.1	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	none
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
Digital Mammography X-Ray Image Storage - For Presentation	1.2.840.10008.5.1.4.1.1.1.2	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	none
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
Digital Mammography X-Ray Image Storage - For Processing	1.2.840.10008.5.1.4.1.1.1.2.1	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	none
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
CT Image Storage	1.2.840.10008.5.1.4.1.1.2	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	none
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
Ultrasound Multi frame Image Storage (Retired)	*1.2.840.10008.5.1.4.1.1.3*	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	none
		Explicit VR Little Endian	1.2.840.10008.1.2.1		

Ultrasound Multi-frame Image Storage	1.2.840.10008.5.1.4.1.1.3.1	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	none
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
MR Image Storage	1.2.840.10008.5.1.4.1.1.4	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	none
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
Nuclear Medicine Image Storage (Retired)	*1.2.840.10008.5.1.4.1.1.5*	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	none
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
Ultrasound Image Storage (Retired)	*1.2.840.10008.5.1.4.1.1.6*	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	none
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
Ultrasound Image Storage	1.2.840.10008.5.1.4.1.1.6.1	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	none
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
Secondary Capture Image Storage	1.2.840.10008.5.1.4.1.1.7	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	none
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
X Ray Angiographic Image Storage	1.2.840.10008.5.1.4.1.1.12.1	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	none
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
X-Ray Radiofluoroscopic Image Storage	1.2.840.10008.5.1.4.1.1.12.2	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	none
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
Nuclear Medicine Image Storage	1.2.840.10008.5.1.4.1.1.20	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	none
		Explicit VR Little Endian	1.2.840.10008.1.2.1		

Presentation Context Acceptance Criterion

Any number of verification or storage SOP classes that are listed above will be accepted by the *ACOM.Convert*, while there are enough resources on the local host.

Transfer Syntax Selection Policies

The *ACOM.Convert* currently supports the Implicit VR Little Endian and the Explicit VR Little Endian transfer syntax. Any proposed presentation context which includes one of these transfer syntaxes will be accepted. Any proposed presentation context that does not include one of these transfer syntaxes will be rejected. If both of them are proposed, Explicit VR Little Endian transfer syntax is selected.

Communication Profiles

Supported Communication Stacks

The *ACOM.Convert* provides DICOM V3.0 TCP/IP Network Communication Support as defined in Part 8 of the DICOM Standard.

OSI Stack

Not yet supported.

TCP/IP Stack

The *ACOM.Convert* uses the TCP/IP Stack from MS Windows (WSock32.DLL).

API

The CRS uses the WSock32.DLL.

Physical Media Support

The CRS is independent of the physical medium over which TCP/IP executes. This feature is inherent in the MS Windows operating system.

Point-to-Point Stack

Not supported.

Extensions / Specializations / Privatizations

Not applicable.

Configuration

AE Title / Presentation Address Mapping

The *ACOM.Convert* maps Application Entity Titles to TCP/IP address and port number via an internal configuration method.

Configurable Parameters

- Local AE Title
- C-STORE Retry Count and Interval

Support of Extended Character Set

The application supports the ISO 8859 Latin 1 (ISO-IR 100) character set.

Appendix

Requirements for the Image-Pixel-Modules

- **Photometric Interpretation** (0x0028/0x0004) must be one of: "MONOCHROME1", "MONOCHROME2" or "RGB".
- **Planar Configuration** (0x0028/0x0006) must be '0000'.
- **Bits Allocated** (0x0028/0x0100) must be '8' or '16'.
- **Bits Stored** (0x0028/0x0101) must be between '8' and '16'.

MEDIMAGE®

THE IMAGE MANAGEMENT SYSTEM

DICOM Archiving & Viewing Station

Software Vers. 4.42

Date of issue: 26.01.2000

CE 0535

User-Manual

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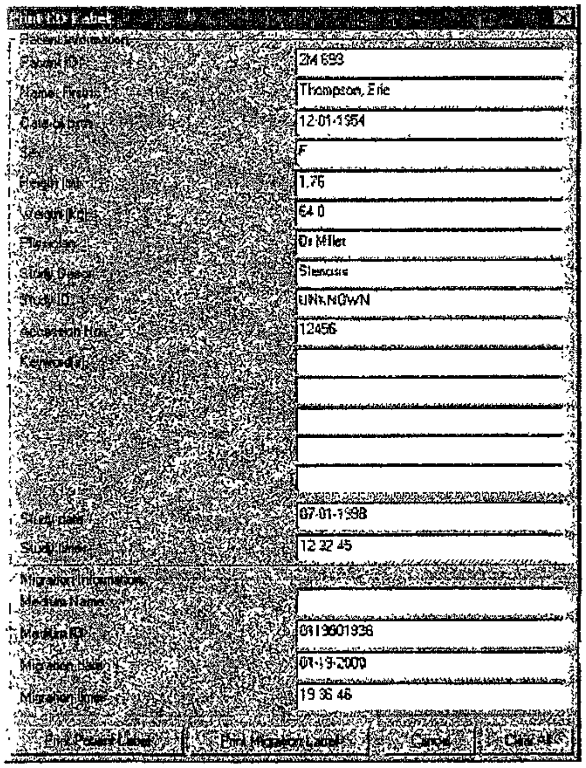
WEB: http://www.vepro.com

VEPRO
COMPETENCE IN IMAGING

Exhibit 241

COD 0099630

CD-Label Print



To print a new CD-Label (for copied CDs), press this button . Make sure that the labels are inserted in the right printer slot and in the right direction. Following window comes up, to change the patient or migration data, printed on the CD-Label:

In this dialog box two areas are available to enter data for printing either a patient label or a label for a migration medium. In the upper area the patient information is entered, In the lower area the correct data for a migration media.

After entering the correct data, a CD-Label is printed on the connected printer (if available).

Send DICOM Echo

To check if the DICOM modality is connected and responding to the Archiving System, press this button . If the physical connection and the configuration for the DICOM transmission is correct a message is displayed. If there is any failure mentioned check your DICOM TCP-IP address, the DICOM Port Number, and the DICOM AE-Title of both systems (Sender and Receiver).

NOTE: If the Archiving System is connected directly to the DICOM modality (without using a Network-HUB or SWITCH) a "Crossover" network cable must be used for a connection.

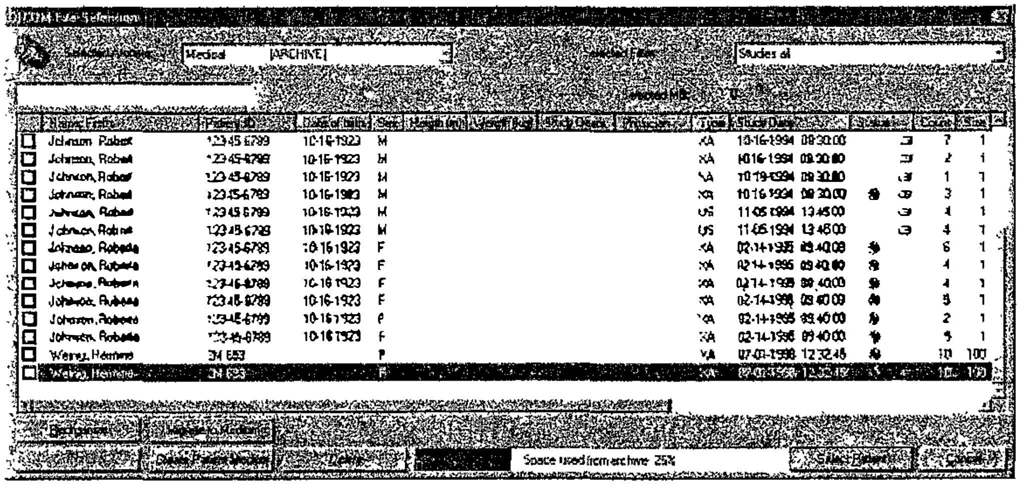
Failed DICOM Transfer

On selecting this symbol  a window opens displaying the names of the patient studies not transferred to the DICOM network due to a transfer error.

Here you have the possibility to select a patient study and send it again. To cancel the transfer of the patient to the DICOM network, the patient can be deleted from the list.

Display images from the archive

To access the archive, click on the symbol in the standard toolbar or choose *File* menu option *Open Archive*. The following dialog box appears:



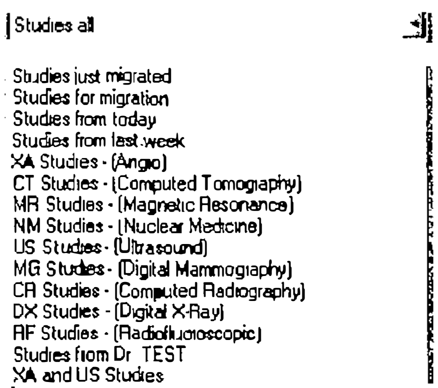
Select Archive

If different archives (local drive, server) are configured it is possible to choose in what archive your want to search for.

Selected Filter

Several filters are available for the database. You can choose one of the listed filters to display only the sequences which fit the criteria. For example all studies from any patient are displayed using the filter "Studies all". If only the non-migrated (not yet archived on CDs or DVDs) should be displayed change the filter to "Studies for migration". In result you see all studies which must be migrated to any long term archive media.

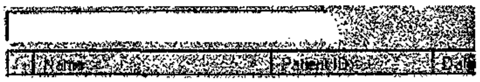
Please ask your system administrator if other filters must be defined especially for you:



Search criteria

To define with what search criteria you want to search for, different search possibilities are available:

While clicking on the column description the search in this column is activated (displaying green background) and sorted upwards. With a next click, this column is sorted downwards. If you activate by example the PatientID column, you can enter in the data field above



the search keyword. After entering some characters automatically the patient with this existing ID is displayed. With a double click on the study to this patient the ICONs are previewed, and the images or sequences can displayed as usual.

Select patient

To get image- or film sequences of a patient, select the corresponding patient from the list and click on the button ***Select Patient.*** Alternatively you can double-click on the patient study in the list.

Delete

To delete a patient study from the archive, you must enable this at first in the Menu Bar under the section *View* with the option *Enable deleting of series.* After entering a password studies can be deleted. Click on the patient study and press the *Delete* button. To disable the deletion possibility, click again the option *Enable deleting of series*.

Please ask your Archiva Administrator for the correct password.

Create Media

Differences between Migrate to Medium and Create Patient medium

Migrate to medium

Migration copies all selected studies to a long term archive (CD / DVD) and creates a medium what MUST be used in the "shelf archive" – or into a "Jukebox".

Note: **It makes always sense to create a copy of such a Migration Medium and store this at a other location for safety reasons.**

After a successful migration in the status column a medium symbol is displayed and a migration no. (00001 – 99999) plus a migration ID is created for this medium.

Note: **Only if a migration to a long term medium was made, the system is able to move out this study from the FIFO (First In First Out) archive.**

Never take a migration medium as an exchange media to a third party – it is the only real archived medium for a later image retrieval and or for a database recovering.

Create patient medium

This function allows to create a medium with one, or several patients on it. Automatically the viewing software is also copied to this medium allows –a patient or an other hospital – to view this images with inserting this medium into a normal PC.

Note: **This functionality does not change any archive status – it is only a copy of the archived data on the disc.**

Migrate to Medium

If one or several studies are to migrate to a long term archive media like CD or DVD (optional) then each of the studies must be marked with a click on the square box in front of the patient name.

For writing CDs you can mark up to 600 MB data, for writing DVDs you can mark up to 2,5 GB totally.

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(43) **Pub. Date: Jul. 4, 2002**

(54) **MEDICAL DATA RECORDING SYSTEM**

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(52) U.S. Cl. **369/124.07**; 369/99

(57) **ABSTRACT**

A device for recording information on CDRs or other recording media and printing file information for observing what is recorded thereon. The information may be medical images such as x-rays, cat scans, magnetic resonance images, or sonograms. The discs can have patient names and other information selected from information stored thereon, printed on the disc as well as logos for the hospital, service provider or trademarks. The discs can be automatically loaded into the recorder and printer. The fields of information or logos printed on the discs can be changed to suit the user. A database creates and updates a directory of patent files so the discs can be located and the images thereon viewed for each patient. The discs have software allowing the computer to view the images on the disc so that a personal computer not having imaging software can operate the disc. The image information can be downloaded from a remote imaging machine for storage.

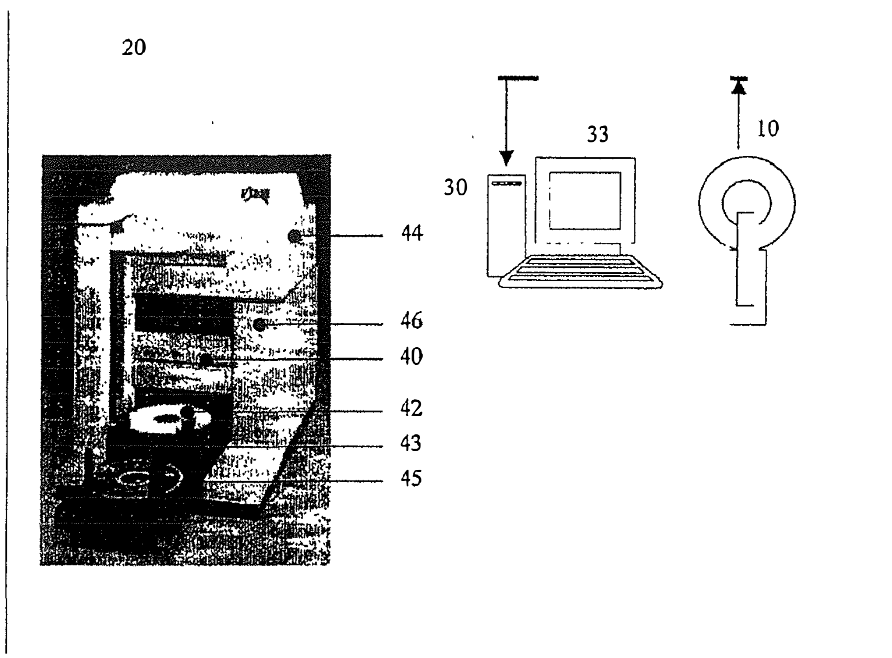
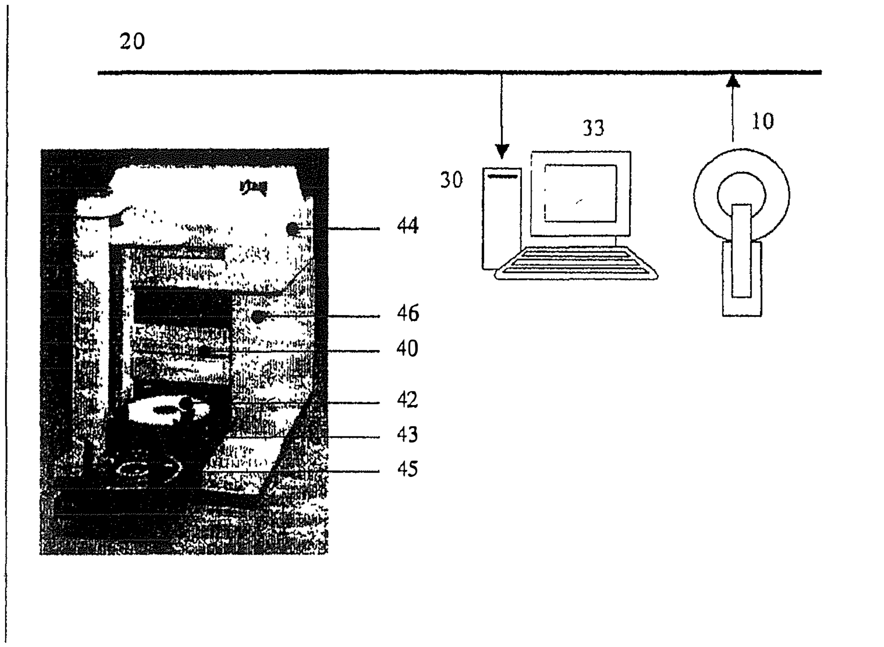


Exhibit 256

PG 000144

Figure 1.



PG 000145

Figure 2.

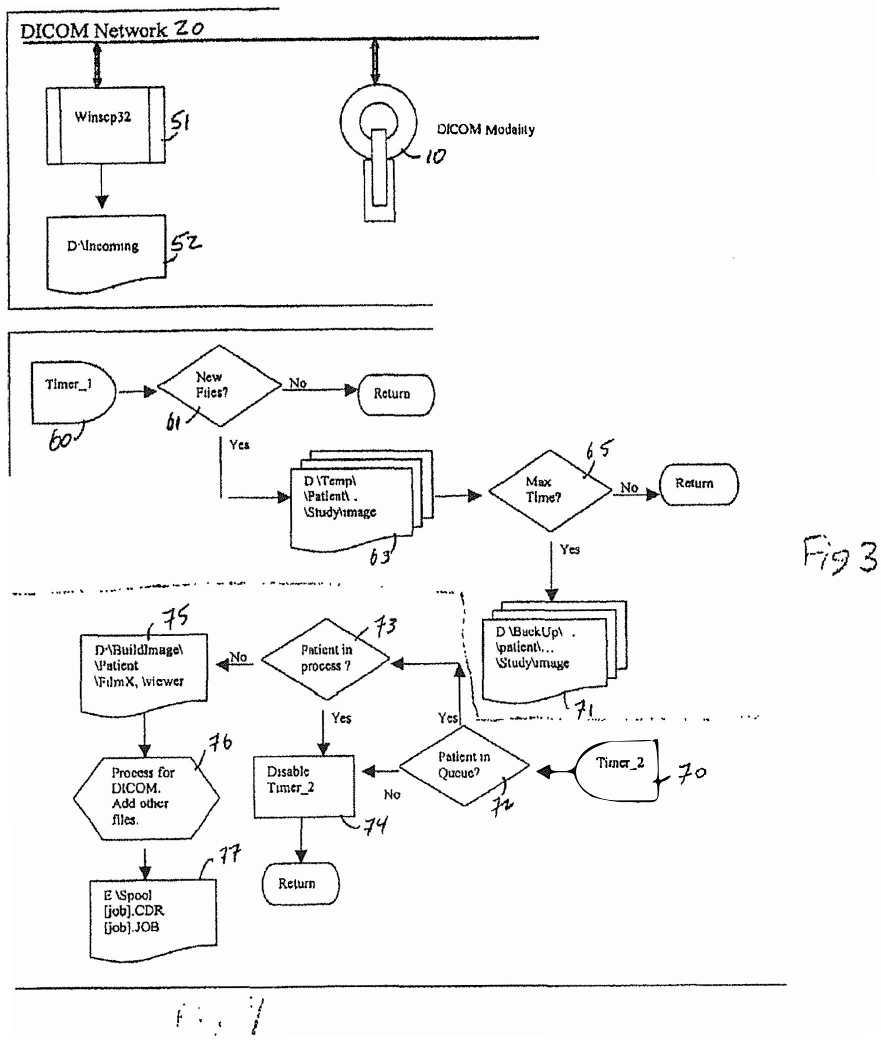
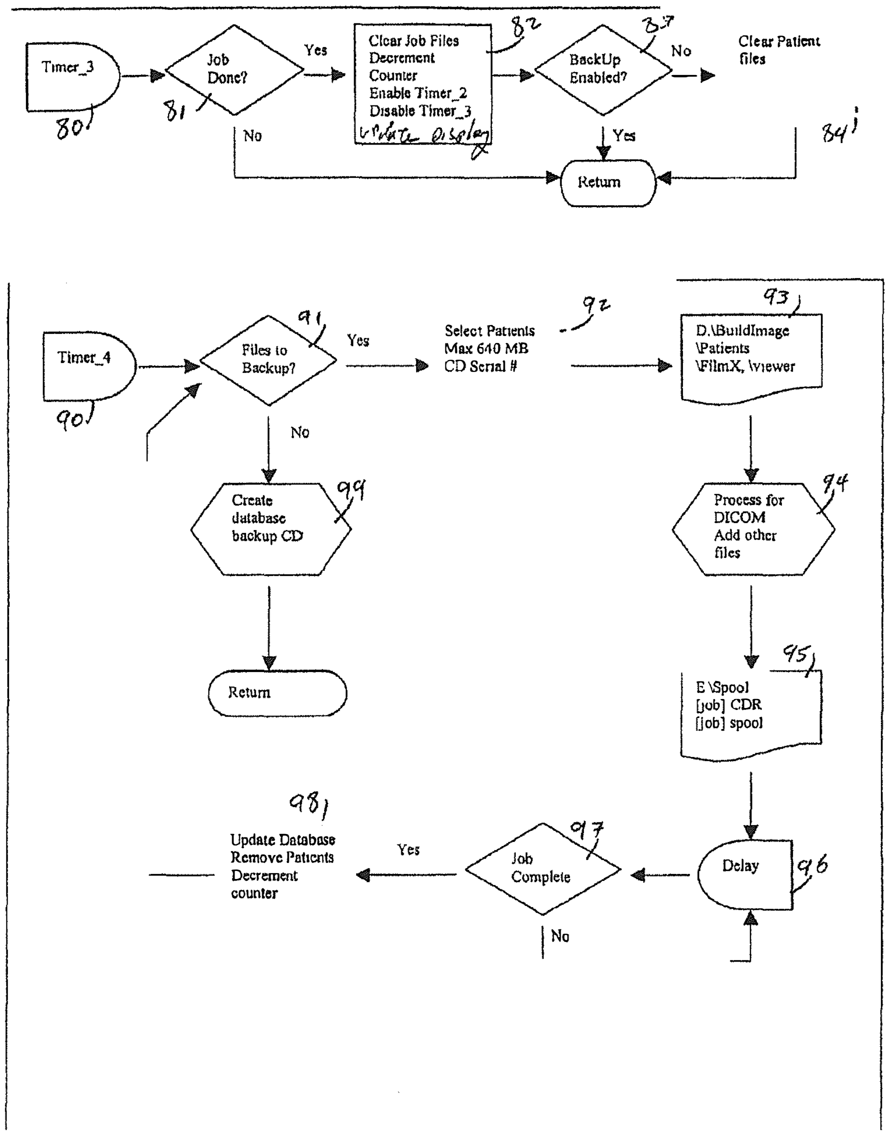


Fig 3

Fig 1

Fig 5



Timer_3
80
Job Done?
81
Yes
No
Clear Job Files
Decrement Counter
Enable Timer_2
Disable Timer_3
Update Display
82
BackUp Enabled?
83
No
Yes
Clear Patient files
84
Return
Timer_4
90
Files to Backup?
91
Yes
No
Select Patients
Max 640 MB
CD Serial #
92
D:\BuildImage
\Patients
\FilmX, \viewer
93
Create database backup CD
99
Return
Process for DICOM
Add other files
94
E:\Spool
[job] CDR
[job] spool
95
Delay
96
Job Complete
97
Yes
No
Update Database
Remove Patients
Decrement counter
98

MEDICAL DATA RECORDING SYSTEM

BACKGROUND OF THE INVENTION

[0001] 1. Field of the Invention

[0002] This invention relates to data storage and more particularly to determining end of incoming data stream in order to create jobs for recording and printing file information on a disc taken from the electronically stored information on the disc.

[0003] 2. Description of the Related Art

[0004] In the past medical imaging such as x-rays were recorded on film and digital images were stored on digital film using film laser printers, which is expensive, bulky and difficult to store. Also, the original digital data might have to be modified so it can be printed using a laser printer since most printers can not handle high resolution or high quality digital data. Digital image storage allows storage and retrieval of original digital data on discs and transmittal of images over communications systems such as the internet.

[0005] There are printers combined with CD recording devices for printing on the disc that has just been recorded.

[0006] Medical imaging data is frequently manually stored on CD's and filed for later use in doctor's offices, hospitals, clinics and other medical facilities. The medical images may be generated by x-rays, cat scans, magnetic resonance images, sonograms or other image generating technologies.

[0007] Medical imaging data can be transmitted from one location to another over the internet or other communication system for recording the data. The filing and record keeping of the images thus received is a problem. It is a labor-intensive and error-prone task to gather information about each disc, write out labels and attach the labels to the discs, or write directly on the disc for storing and filing. It is very useful to have the information contained on a disc printed on the disc for reference and filing and for automatically creating a directory of the information stored on all the discs recorded in an office.

SUMMARY OF THE INVENTION

[0008] The present invention automatically scans data received for storage on the disc and prints selected fields of information directly on the discs for ease of file management. II The invention also constantly updates a database having a directory of all patient records and the discs the patient data is stored on. Although the invention is described in terms of storing medical imaging data any data imbedded with information useful for filing and label printing can be used with the invention.

[0009] The Medical Data Recording System hardware consists of three main components: a computer server; a CD autoloader with printer; and a piracy prevention device. The software components are: DICOM® communication software; FilmX™ software for storing software for viewing the images on the CDs, software for selecting image information to be copied to the CD and fields for printing on the discs; software for creating and updating a database of patient information and autoloader control software for the CDR and printer; and security device driver software.

[0010] The computer server communicates with other medical devices on the network using the DICOM® protocol. It receives medical images (patient studies) from other devices, processes the images and burns each patient's images on one or more CDRs along with medical image viewing software and other files as defined by the DICOM® protocol as well as files containing printed label definition and graphics files, files containing patient and study demographics, and necessary system files to make the CD autorun and autoload. Once a CDR has been burnt, information regarding the contents of the CDR and other graphics (company logo, legal notices, etc) is then printed directly on the CDR using the printer attached to the autoloader. Optionally, the system will create back up copies of the medical images it has received by burning them on CDR at configured days of the week and time. Each back up CDR will contain as many patients' images as possible to maximize disc space usage. Each backup disc is assigned a serial number which is printed on it. The patient and study demographics of the backed up data along with the corresponding backup disc serial number is stored in a database where they can queried.

OBJECTS OF THE INVENTION

[0011] It is an object of the invention to print information from selected fields of data saved on a disc onto the disc for visual recognition such that the discs can be properly stored in files.

[0012] It is an object of the invention to reduce clerical time and reduce errors by having discs printed with information fields from files stored on the discs.

[0013] It is an object of the invention to automatically load discs for information storage.

[0014] It is an object of the invention to automatically stop recording when the information stream has stopped and load a new disc for the next patient.

[0015] It is an object of the invention to print trademarks, service marks and logos on the discs.

[0016] It is an object of the invention to print selectable fields of information on the discs.

[0017] It is an object of the invention to back up files at specified time intervals.

[0018] It is an object of the invention to get as many images as possible onto one CDR.

[0019] It is an object of the invention to conveniently store medical image data on CD's rather than on film.

[0020] It is an object of the invention to be able to use a computer display to view medical images stored on CD's.

[0021] It is an object of the invention to preserve medical images for long periods of time.

[0022] It is an object of the invention to create patient files with directories and subdirectories from image data streams.

[0023] It is an object of the invention to divide data streams into separate files.

[0024] It is an object of the invention to automatically create and update file databases to locate patient information on the discs.

[0025] Other objects, advantages and novel features of the present invention will become apparent from the following detailed description of the invention when considered in conjunction with the accompanying drawing.

BRIEF DESCRIPTION OF THE DRAWINGS

[0026] **FIG. 1** shows a schematic of the system using the data recording system.

[0027] **FIG. 2** shows a block diagram of the software steps used in the computer for receiving files from the network and storing them on the computer.

[0028] **FIG. 3** shows the routine for determining the data for jobs from incoming files.

[0029] **FIG. 4** shows the routine for processing jobs in queue.

[0030] **FIG. 5** shows the routine for checking for end of jobs.

[0031] **FIG. 6** shows the routine for the backup process.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0032] **FIG. 1** shows a schematic view of the invention. A medical imaging device **10** such as an x-ray, cat scan, magnetic resonance imaging, sonogram or other device which generates information for storage on a disc generates images of a patient and either transmits it or stores it for later transmittal through a communication network **20** such as the internet to a computer **30**. The computer **30** can be used to select information to be stored by the compact disc writer **40** on compact discs, CDs, **42** and can select what information is to be printed by printer **44** on discs **42**. Although CDs **42** are shown, any recording medium may be used for storage of information. The blank compact discs **42** are stacked in an input CD stack **43** waiting to be recorded. The CD autoloader **46** selects CDs **42** from the top of the input CD stack **43** to be recorded on and places the CDs **42** into the recorder **40**. When the CD **42** has information stored on it, it is moved by the CD autoloader **46** to the printer **44** where selected information and logos or other graphics are printed on the CD **42** so that the users have a written record on the disc of the information stored thereon and logos identifying the producer of the disc or other information. The CDs **42** are then removed from the printer **44** by CD autoloader **46** and placed in the CD output tray **45**. The CDs **42** can then be placed in patient files.

[0033] The software for running the invention performs several tasks. There is security software communicating to an attached piracy prevention security device that keeps track of how many CDs are being recorded and what product option are active. There is software to run the autoloading functions of the CD autoloader **46** for recording and moving discs **42**. The software also can be programmed to select the fields of information to be printed on the discs and for printing logos or other graphics or information on the discs. The software also copies instructions for operating the imaging onto the disc so that a computer without imaging software loaded in it can view the images on the discs.

[0034] Although many different software programs can be used to accomplish the goals set out above the following shows one method of securing image information for later viewing and recording it on discs with labels printed thereon. The software described herein is called FilmX™ software by the applicant.

[0035] FilmX™ software is used to receive data in the computer **30** from the communication network **20**. The software incorporates DICOM® network connectivity software **51** such as WinSCP32.exe which is currently a standard digital imaging protocol used in the industry to receive the digital imaging data from the imaging device **10**. The imaging data is received in the computer **30** by use of network connectivity software **51** using "winSCP32.exe" software available from ETIAM Corporation; Rennes, France. This program is a Storage Service Class Provider using the DICOM® protocol. The computer **30** receives DICOM images that are sent to it and places them in the Incoming ("D:\Incoming") directory **52**. The files are named:<Storage SOP Class>.<SOP Instance UID>.dcm where <Storage SOP Class>is the SOP class of the image and <SOP Instance UID>is the image UID (Unique Identifier).

[0036] There are multiple timers defined with in FilmX.exe. Timer_1 **60** is responsible for checking for incoming new files **61** in Incoming Directory **52**. If new files are received they are stored as a separate file in a temporary directory Temp Directory **63**. Timer_1 **60** is programmed to check if an end-of-patient-data timeout (MaxTime) **65** has occurred. The value for Timer_1 **60** is defined in the FilmX.ini file and is hence user configurable. Default time for Timer_1 **60** is 1 (one) second. Max Time **65** is also user configurable via FilmX.ini and is set to 30 seconds for default. The system will not allow that time to be set less than 10 seconds. Once the Timer_1 **60** goes off, two routines are called:

[0037] DcmBTreeParseInputDirectory

[0038] dcmBTreeMakePatientDataAvailable

[0039] The first routine parses any DICOM Part 10 file found in Incoming Directory **52**. If any new files **61** are available, they are transferred to the Temp Directory (d:\Temp) **63**. For each different patient, a subdirectory is created under the Temp Directory **63**, and for each study of this patient, a subdirectory is created under the patient directory.

[0040] Patient differentiation is based on Patient Identification which consists of the concatenation of information found in DICOM datasets: PatientsID '_' PatientsName, without any '^', any white character or any character that may lead to an invalid Windows directory name, all characters are uppercase and enclosing blanks are removed. Patient Directory name underneath Temp Directory **63** is the Patient Identification described above.

[0041] Study identification is based on the StudyInstanceUID. Study Directory name beneath the Patient Directory is the study identification referenced above.

[0042] Filenames are the original filenames found in Incoming Directory **52**. This allows the system to override an image if it is sent twice.

[0043] An additional text file is created in each Patient Directory. This file has a fixed name (timestamp.bsy) and contains the date and time of the last image insertion in the Patient hierarchy. The following information is also written in this file:

[0044] PatientsName

[0045] PatientsSex

[0046] PatientsBirthDate

[0047] An additional text file is created in each Study Directory. This file has a fixed name (study.dsc) and contains the information extracted from the last image of the study inserted in the Study Directory. This information is as follows:

[0048] StudyDate

[0049] StudyTime

[0050] StudyID

[0051] StudyDescription

[0052] RefferringPhysiciansName

[0053] AccessionNumber.

[0054] Once DcmBTreeParseInputDirectory has returned, any new patients are added to the Incoming Patient Queue and displayed on the screen as such. The combination of patient "[id]_[name]" is now the internal job name used for tracking the job.

[0055] Then dcmBTreeMakePatientDataAvailable is called to check in Temp Directory **63** if any patient subdirectories have not been modified (some images added) since MaxTime **65** seconds ago. The number of unmodified directories since MaxTime **65** seconds is returned. If no new files **61** have arrived for a patient, the timestamp file (timestamp.bsy) for the patient will be renamed to a fixed filename (timestamp.rdy).

[0056] Once the function returns a positive number, we browse for Patient Directories in the Temp Directory **63** containing "timestamp.rdy" file. The entire patient hierarchy is then moved to the Backup Directory **71** (D:\Backup). The Job is then removed from the Incoming Patient Queue and added to the Pending Patient Queue and displayed as such. If inactive, Timer_2 **70** is activated to start processing the pending job(s).

[0057] Timer_2 **70** is responsible for moving jobs pending in Queue to be processed. Once it goes off, the system is checked for any patient in queue **72**, if none are present, Timer_2 **70** is disabled in step **74**. If there are pending jobs in Pending Patient Queue, the system is checked for patient in process **73** (being recorded or printed). If there is one, Timer_2 **70** is disabled and it returns. If there are no patients in process **73**, the next job in Pending Patient Queue, is processed. The patient directory hierarchy in Backup Directory **71** is moved to the Build Image Directory **75** (D:\Build Image) to get ready to burn on CDR(s). The Build Image Directory **75** also contains a Viewer Directory ("\Viewer) where the viewing software resides. There is also a FilmX Directory ("FilmX") in the Build Image Directory **75** which contains the Patient information file ("Patient.txt") and the Xlabel Directory ("\Xlabel") where the CD printing label definitions and graphics files reside. Since DICOM Exchange standards only allow for eight character file names, the Patient, and Study directories as well as image file names are converted to eight character format in processing step **76**. The Patient Directory name is changed to "PT000000" for the first patient. In case of back up CD, Patient Directories are then sequentially named "PT000001" and so on. The Study Directory(ies) are named starting with "ST000000" and increase sequentially if there is more then one study for the patient. The image files are then named starting with "IM000000" and so on. On the Build Image Directory **75** there is also an "autorun" file which is recognized by the Windows operating system and executed when a disc is inserted in a computer. The "autorun" file contains instructions to start the viewer in an "autoload" fashion causing it to immediately load and display the first Patient's first Study. Finally, according to DICOM Exchange standard, a "DICOMDIR" file in generated in step **76** in the Build Image Directory **75**.

[0058] Once the Build Image Directory **75** is complete, it represents what should be put on the final CDR with Build Image Directory **75** as the root of the CD. The computer program "Premaster.exe" is then called to create a CD image of the contents of the Build Image Directory **75**. This program is part of the BuzzSaw® software package produced by ISO Media of Seattle, Wash. The result is a "[job].CDR" file which is the image of the final CDR. It is located in the Spool Directory **77** (E:\Spool). A "[job]job" file containing the job control information for the autoloader control software (Buzzsaw®) is created in the Spool Directory **77**. The Job file specifies the name of the CDR file, the input file for the print label fields, the number of CDRs to be made, the test flag, and other fields as required by the Buzzsaw® software. Once the CD image files is generated in the Spool Directory **77**, the Build Image Directory **75** is then cleared of the patient directory and other created files. Once created, the job file is recognized by the Buzzsaw software and processed.

[0059] Buzzsaw® instructs the autoloader **46** to pick up a new CDR **42**, put it in the CDR drive **40**. Once there, Buzzsaw® will proceed to record the contents of [job] .CDR" file on the CDR **42** in the drive **40**. In multi-copy, multi-drive situations, Buzzsaw® will place new CDRs **42** in other drives **40** as well and record them simultaneously. Once the recording is finished, Buzzsaw instructs the autoloader **46** to place the recorded CDR **42** in the Disc Printer **44**. It will then execute the printing software to print the label containing the input fields on the CDR.

[0060] The label printing software and printer driver are supplied by Primera Technologies; Plymouth, Minn., a disc printer manufacturer. The label definitions allow for input fields to be merged into the label via a merge file in Build Image Directory **75**. The patient.txt file in the Build Image directory **75** is that merge file.

[0061] Once printed, the CDR **42** is then placed in the output bin **45** by the autoloader **46**. If there are multiple copies, the other CDRs **42** are then printed by the Disc Printer **44** and put on the output bin **45** as well by the autoloader **46**. Buzzsaw then updates the status line at the bottom of the "[job].JOB" file contained in the Spool Directory **77** to indicate the job is completed.

[0062] Timer_3 **80** is responsible for checking the end of the job. Once Timer_3 **80** goes off, the system checks for job done **81**. If so, the job is moved from the Patients in Process to Patients completed and display is updated in step **82** where Timer_3 **80** is cleared, and Timer_2 **70** is enabled. If Backup Enabled **83** is false, the patient directory is deleted from Backup Directory **71**. Otherwise, it will be kept there to be used during the backup.

[0063] Timer_4 90 starts the backup process. It is programmed to go off at the configured time on the configured day(s) of the week. The program then checks if there are any files to backup 91. This is also a check for the end of back up process. If finished (or nothing left to back up), a CDR 42 containing only the latest database files is generated 99. This is the backup disc for the database files. If there are files to backup 91, in Select Patients step 92 enough patients are selected to fill a 650 MB CD (if there are enough) minus approximately 10 MB which is used for storing system, label, and viewer files. A Backup CD unique serial number is also generated in Select Patients step 92. The patient directories are then moved from Backup Directory 71 to Build Image Directory 75. The same processing as for a patient CD, as described in steps 75-77 above then occur steps 93-95. Once a backup job is created, the software then goes through a timed delay 96 waiting for the job to finish by checking for job complete 97. Once done, the database is updated with the patient and study information of all the patients on that CD and the CD unique serial number in Update Database step 98. The process starts anew by checking to see if there are any more files to back up 91.

[0064] A simple query screen allows for querying the backup database using patient name, patient id, or study date thus allowing the user to find which CD a patient information is stored on.

[0065] The piracy protection device is attached to the parallel port. It is initialized with the number of CDRs 42 purchased, and with patient and/or backup options. FilmX will create patient CDs if that option is enabled; back up CDs if that option is enabled; and ii both if both options are present. Once a job has been successfully completed, the number of CDs created by it are deducted from the counter in the piracy protection device. If at Zero, the system halts operation until a new code for additional CDs has been entered. Patient and/or backup options can be enabled by operator entering a code provided by Soma Corporation.

[0066] Even though the invention has been described herein using CDRs, other printable recording medium, including but not limited to CDR, CDRW, DVD-R, DVD-RW, DVDRAM; can be used.

[0067] Obviously, many modifications and variations of the present invention are possible in light of the above teachings. It is therefore to be understood that, within the scope of the appended claims, the invention may be practiced otherwise than as specifically described.

What is claimed is:

1. A data recording system comprising:

a computer for receiving information, including fields of identification data to identify the information received,

a means for dividing the received information into one or more identifiable files for a job,

a information recorder for storing the identifiable files of the job on a data storage medium, and means for recording the information on the data storage medium,

a means for selecting fields of identification data from the information received, for printing on the data storage medium,

a printer for printing selected fields of identification data on the data storage medium and for printing other matter such as logos on the data storage medium,

a means for instructing the printer to print the selected identification data and other matter on the data storage medium.

2. A data recording system as in claim 1 wherein,

the data stored on data recording medium are images and,

a means for recording instructions on the data storage medium for a computer to automatically load the images stored thereon for viewing.

3. A data recording system as in claim 1 wherein,

a timer detects a pause in a data stream to select the end of the data transmitted to the computer for each job.

4. A data recording system as in claim 1 wherein,

a database is created and updated to locate the discs from information stored on the discs.

5. A data recording system as in claim 1 wherein,

a means for selecting the fields selected for printing on the data storage medium is programmed into the data recording system.

6. A data recording system as in claim 1 wherein,

a means for image creation for printing on the data storage medium is programmed into the data recording system for printing logos, trademarks and other images on the data storage medium.

7. A data recording system as in claim 1 wherein,

a means for automatically loading and moving discs to be recorded and printed is employed.

8. A data recording system as in claim 1 wherein,

the job comprises: a job name, a CD image file name, a number of copies of recording media to be created, a label file name, a label merge data file name.

9. A data recording system as in claim 1 wherein,

the job comprises: a job name, a CD file list, a number of copies of recording media to be created, a label file name, a label merge data file name.

10. A data recording method comprising,

receiving data for recording,

organizing the data received into jobs,

storing the data received on a recording medium,

printing selected data received and other information on the medium such that the medium can be identified.

11. A data recording system as in claim 10 wherein,

the job comprises: a job name, a CD image file name, a number of copies of recording media to be created, a label file name, a label merge data file name.

12. A data recording system as in claim 10 wherein,

the job comprises: a job name, a CD file list, a number of copies of recording media to be created, a label file name, a label merge data file name.

13. A data recording method as in claim 10 further including the step of,

creating a data base of patient records to locate the discs the patient images are stored on.

14. A data recording method as in claim 10 further including the step of,

recording software on the medium for viewing the data stored thereon on a computer.

* * * * *

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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

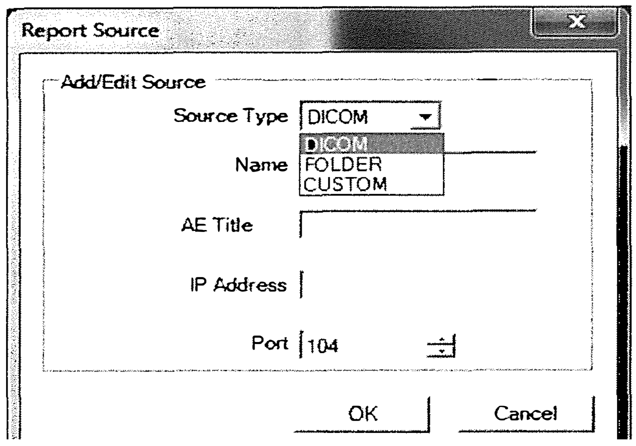
DATCARD SYSTEMS, INC., a California corporation Plaintiff, v. PACSGEAR, INC., a California corporation Defendant. PACSGEAR, INC., a California corporation, Counter-Claimant, v. DATCARD SYSTEMS, INC., a California corporation, Counter-Defendant.	Case No. SACV 10-1288 DOC (VBKx) **DECLARATION OF BRIAN CAVANAUGH** Hearing Date: February 13, 2012 Hearing Time: 8:30 a.m Courtroom of Judge Carter Discovery Cut-Off: Dec. 23, 2011 Trial Date: April 17, 2012

Exhibit 258

Brian Cavanaugh declares and says:

1. I have personal knowledge of the matters stated herein, and, if called upon, could testify to them under oath.

2. Starting with version 3.0, the MediaWriter had the ability to include text reports on a CD/DVD that it is burning, along with previously designated image studies. This feature can be enabled on the MediaWriter using the Report Source dialogue box shown below.



3. The dialogue box above allows a user to specify one of three different source types from which such text reports are to be supplied. The three selectable sources from which to retrieve the text reports we identified as “DICOM”, “FOLDER”, and “CUSTOM”. Each source type is associated with a distinct method by which the text reports for that source type are obtained for inclusion on the CD/DVD. The following is a description of how the MediaWriter retrieves the text report information using each distinct method. Note that these methods cannot cause the retrieval and/or storage of any images onto the CD/DVD.

Source Type: DICOM

4. If the user selects “DICOM” on the Report Source dialogue box, the MediaWriter utilizes a Mitra Report Management protocol (which is a variation on the

DICOM protocol) to request textual information based on the Accession Number of any studies that were selected to be burned onto the CD/DVD.

5. Using the Mitra Report Management protocol, various text data elements are requested and returned from the source – the Mitra Broker. The DICOM Conformance Statement for the Mitra Broker, on page 46, defines the data provided by a Mitra Report Management request. (Exhibit 260). The SOP Class UID, an identifier that specifically defines the type of DICOM message being used, is shown below.

Mitra Report Info Model –FIND	1.2.840.113532.3500.8	all from Table 63	SCP	None

6. In the specification for the Mitra Report Management protocol shown in the Conformance Statement on page 46 and 47, all of the values available using this service are specified. All values are string values and no image data can be retrieved using this service.

7. More specifically, with respect to the MediaWriter code, Jack Goldberg Initial Report, on page 23, lines 14-16, correctly describes that for DICOM Report Sources, a MITRAReportManager is created to handle the request for data. The MITRAReportManager calls a method MitraReportCFind.ImportReports which handles the communication with a DICOM report source.

8. The SOP Class UID identifier specified above for the DICOM Conformance Statement matches the SOP Class UID that is sent by the MitraReportCFind.ImportReports method within MediaWriter shown on line 54 of MitraReportCFind.cs shown below:

string sop = "1.2.840.113532.3500.8"; // Mitra "1.2.840.10008.5.1.4.31"; //Worklist

9. Note that the second number shown is commented out of the code. No other SOP Class UID identifier is used within the MitraReportCFind class nor the MitraReportManager class of the MediaWriter code.

10. The code for MitraReportCFind.ImportReports is found in the file entitled MitraReportCFind.cs in the MediaWriter code. Starting at line 177, the code shows all of

the values that are retrieved when requesting a text report. There are 15 values in total, and line 177 clearly defines these values as string values, which cannot be images.

```
string pname, patid, studyUID, acc, dob, sex, refphys, resultID, recDate, recTime,
        recorder, intAuthor, intID,intText, impressions;
findres.GetS(0x0010, 0x0010, out pname);
findres.GetS(0x0010, 0x0020, out patid);
findres.GetS(0x0020, 0x000d, out studyUID);
findres.GetS(0x0008, 0x0050, out acc);
findres.GetS(0x0010, 0x0030, out dob);
findres.GetS(0x0010, 0x0040, out sex);
findres.GetS(0x0008, 0x0090, out refphys);
findres.GetS(0x4008, 0x0040, out resultID);
findres.GetS(0x4008, 0x0100, out recDate);
findres.GetS(0x4008, 0x0101, out recTime);
findres.GetS(0x4008, 0x0102, out recorder);
findres.GetS(0x4008, 0x010C, out intAuthor);
findres.GetS(0x4008, 0x0200, out intID);
findres.GetS(0x4008, 0x010B, out intText);
findres.GetS(0x4008, 0x0300, out impressions);
```

11. Accordingly, neither the MitraReportManager class nor the MitraReportCFind class provides the MediaWriter with the ability to request or retrieve image studies. Thus, a user is not able to retrieve image studies by configuring the MediaWriter through Source Type: "DICOM" above.

Source Type: FOLDER

12. If the user selects the "FOLDER" source type on the Report Source dialogue box, the user causes the MediaWriter to gather HL7 reports that have been previously sent to the MediaWriter system and received by a separate service, HL7ReportService, that runs continuously to receive HL7 formatted reports. The HL7ReportService receives text data in HL7 messages. The text data is retrieved from the HL7 messages and then stored in its own HTML formatted file under a configured reports folder on the hard drive of the MediaWriter. The folder path and file name of the HTML formatted file are defined by the Patient ID and Accession number of each received HL7 report. Image data cannot be

retrieved from the HL7 message, and no image data is written to the HTML formatted file by the MediaWriter.

13. When the "FOLDER" source is selected as the source type, the MediaWriter goes to the report folder associated with HL7 Report for the Patient ID and Accession Number associated with each study the user has selected for burning onto the CD/DVD. If a file exists in the folder, the MediaWriter copies it to the CD/DVD. No image studies can be requested or retrieved using the Source Type: Folder.

Source Type: CUSTOM

14. The "CUSTOM" source type on the Report Source dialogue box allows the MediaWriter to retrieve reports using a PACS's custom report interface. The only custom interface that has been developed (and thus available for use) is to the iSite PACS from Philips Medical Systems.

15. With respect to the MediaWriter software, when reports are enabled with the CUSTOM source type image data is burned to a CD/DVD, an instance of the CustomReportManager class is created. The source code for this class is stored in the file entitled "CustomReportManger.cs". If the Source Type "Custom" is appropriately configured the MediaWriter calls a method entitled CustomReportManager.ImportReports()" to retrieve iSite related reports. This method calls an external application entitled "iSiteReportEx.exe", written by PACSGEAR, to retrieve text report data from an iSite PACS. The source code for this program is stored in the file entitled "Program.cs". The application iSiteReportEx.exe utilizes an Application Programming Interface (API) provided by the iSite PACS product that allows the retrieval of textual report data. The relevant page of the iSite API specification is shown in Ex. 261.

///

///

///

16. The return value from the report call is shown below as a string value, and as explicitly stated, the string is raw report text.

Return Values:

Value	Meaning
String	XML string that contains raw report text
""	Empty string, use GetLastErrorCode() to determine the error.

17. The iSite API does not provide the ability to retrieve any image data from the iSite PACS using this API call, nor does the MediaWriter have the ability to obtain and store image data related to iSite reports to a CD/DVD. Accordingly, no image studies can be requested or retrieved using the Source Type: Custom.

18. Exhibit 217 is a true and correct copy of the MediaWriter's User's Guide for Version 4.0.

19. Exhibit 259 depicts true and correct copies of sample dialogue boxes presented by the MediaWriter to a user in connection with allowing the user to select what he wants to burn on to a CD/DVD including the option to select image studies, Structured Reports or images that have been scanned into a PACS archive.

I declare under the penalty of perjury under the laws of the United State that the foregoing is true and correct. Signed, this 16th day of January, 2012 at Pleasanton, CA.

Brian Cavanaugh

US007783174B2

(12) **United States Patent**
Wright et al.

(10) **Patent No.: US 7,783,174 B2**
(45) **Date of Patent: *Aug. 24, 2010**

(54) **SYSTEM AND METHOD FOR PRODUCING MEDICAL IMAGE DATA ONTO PORTABLE DIGITAL RECORDING MEDIA**

(75) Inventors: **Ken Wright**, Chino Hills, CA (US); **Chet LaGuardia**, Rancho Santa Margarita, CA (US)

(73) Assignee: **Datcard Systems, Inc.**, Irvine, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **12/484,100**

(22) Filed: **Jun. 12, 2009**

(65) **Prior Publication Data**

US 2009/0245754 A1 Oct. 1, 2009

Related U.S. Application Data

(63) Continuation of application No. 11/942,630, filed on Nov. 19, 2007, which is a continuation of application No. 09/761,795, filed on Jan. 17, 2001, now Pat. No. 7,302,164.

(60) Provisional application No. 60/181,985, filed on Feb. 11, 2000.

(51) **Int. Cl.**
H04N 5/91 (2006.01)

(52) **U.S. Cl.** **386/125**; 386/126

(58) **Field of Classification Search** 386/95, 386/125, 126; 705/2, 3
See application file for complete search history.

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(Continued)

Primary Examiner—Huy T Nguyen
(74) *Attorney, Agent, or Firm*—Knobbe, Martens, Olson & Bear LLP

(57) **ABSTRACT**

This application discloses a system for recording medical image data for production on a portable digital recording medium such as CDs and DVDs. This system includes a receiving module, a processing module and an output module, with viewing program for viewing medical image data stored on the portable digital recording medium. It also discloses a method of storing medical image data on a portable digital recording medium, including the steps of receiving the medical image data, processing the data and storing the data on the portable digital recording medium, with a viewing program for viewing medical image data stored on the portable digital recording medium. It further discloses a method of selecting medical image data for recording on a portable digital recording medium, including the steps of connecting a browsing terminal to a computer database that stores the medical image data, selecting a first set of the medical image data from the computer database, and recording the selected first set of medical image data on the portable digital medium, with a viewing program for viewing the medical image data stored on the portable digital recording medium. It also discloses the method and system of retrieving medical image data that are related to the received/selected original medical image data, and recording the original and related medical image data on a portable digital recording medium.

14 Claims, 5 Drawing Sheets

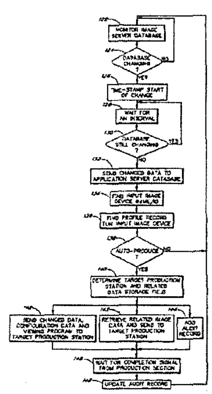


Exhibit 265

Page 660

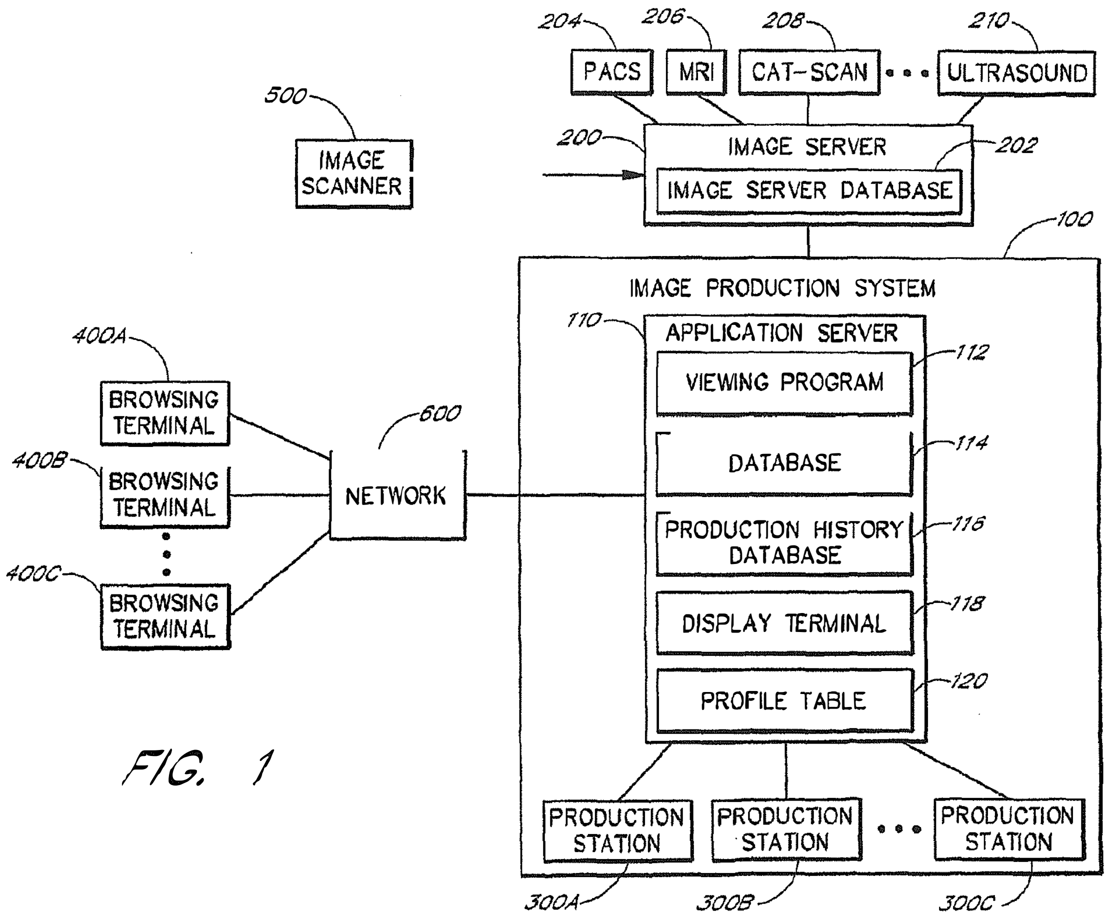

204
206
208
210
PACS
MRI
CAT-SCAN
ULTRASOUND
500
IMAGE SCANNER
200
IMAGE SERVER
202
IMAGE SERVER DATABASE
100
IMAGE PRODUCTION SYSTEM
110
APPLICATION SERVER
112
VIEWING PROGRAM
114
DATABASE
116
PRODUCTION HISTORY DATABASE
118
DISPLAY TERMINAL
120
PROFILE TABLE
400A
BROWSING TERMINAL
400B
BROWSING TERMINAL
400C
BROWSING TERMINAL
600
NETWORK
PRODUCTION STATION
PRODUCTION STATION
PRODUCTION STATION
300A
300B
300C

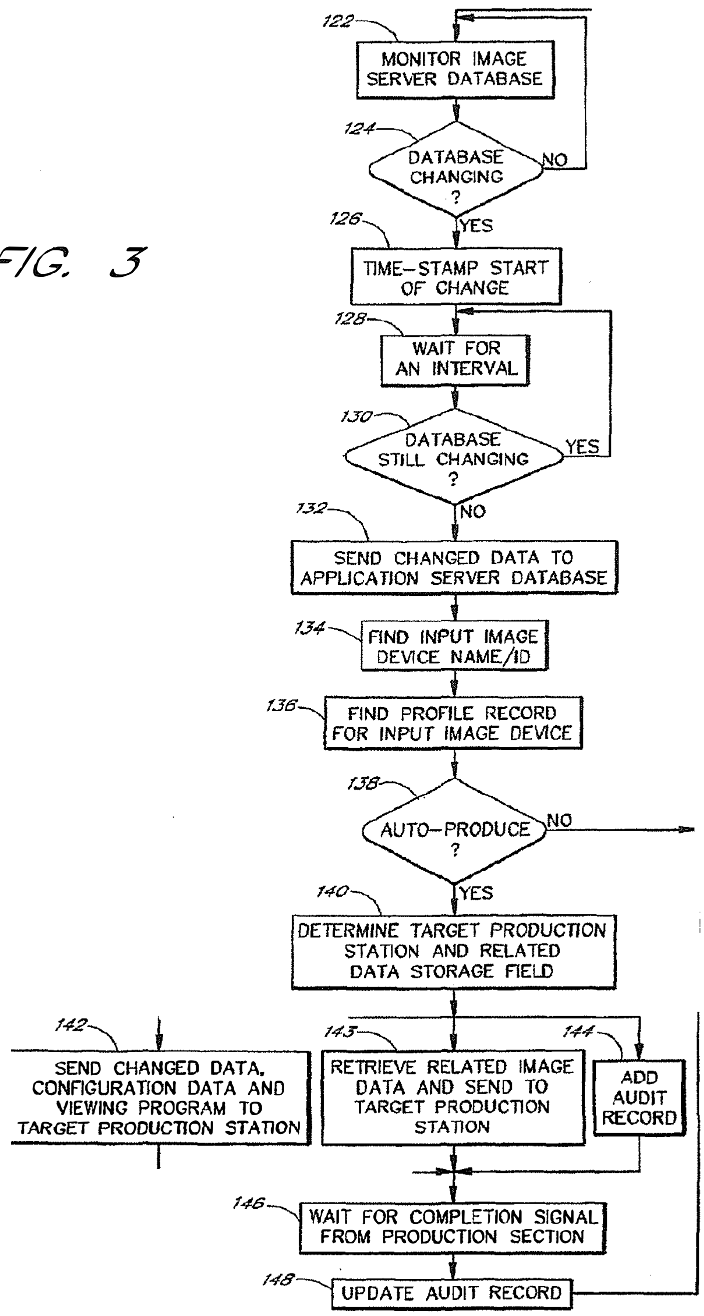
FIG. 1

120

IMAGE INPUT DEVICES \ FIELDS	AUTO-PRODUCE 1 (250)	TARGET PRODUCTION STATION (252)	RELATED DATA STORAGE (254)
MRI MACHINE I	YES	PRODUCTION STATION A	PACS 1
MRI MACHINE II	NO		
ULTRASOUND MACHINE I	YES	PRODUCTION STATION B	PACS 1, PACS 2

FIG. 2

FIG. 3


122
MONITOR IMAGE SERVER DATABASE
124
DATABASE CHANGING ?
NO
126
YES
TIME-STAMP START OF CHANGE
128
WAIT FOR AN INTERVAL
130
DATABASE STILL CHANGING ?
YES
132
NO
SEND CHANGED DATA TO APPLICATION SERVER DATABASE
134
FIND INPUT IMAGE DEVICE NAME/ID
136
FIND PROFILE RECORD FOR INPUT IMAGE DEVICE
138
AUTO-PRODUCE ?
NO
140
YES
DETERMINE TARGET PRODUCTION STATION AND RELATED DATA STORAGE FIELD
142
SEND CHANGED DATA, CONFIGURATION DATA AND VIEWING PROGRAM TO TARGET PRODUCTION STATION
143
RETRIEVE RELATED IMAGE DATA AND SEND TO TARGET PRODUCTION STATION
144
ADD AUDIT RECORD
146
WAIT FOR COMPLETION SIGNAL FROM PRODUCTION SECTION
148
UPDATE AUDIT RECORD

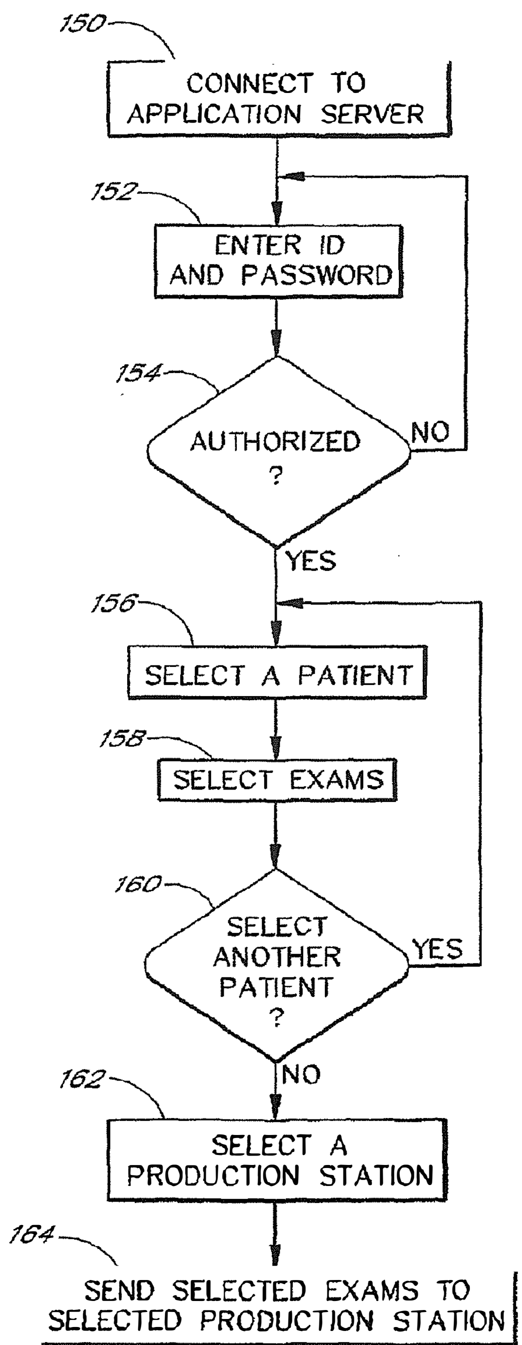

150
CONNECT TO APPLICATION SERVER
152
ENTER ID AND PASSWORD
154
AUTHORIZED ?
NO
YES
156
SELECT A PATIENT
158
SELECT EXAMS
160
SELECT ANOTHER PATIENT ?
YES
NO
162
SELECT A PRODUCTION STATION
164
SEND SELECTED EXAMS TO SELECTED PRODUCTION STATION

FIG. 4

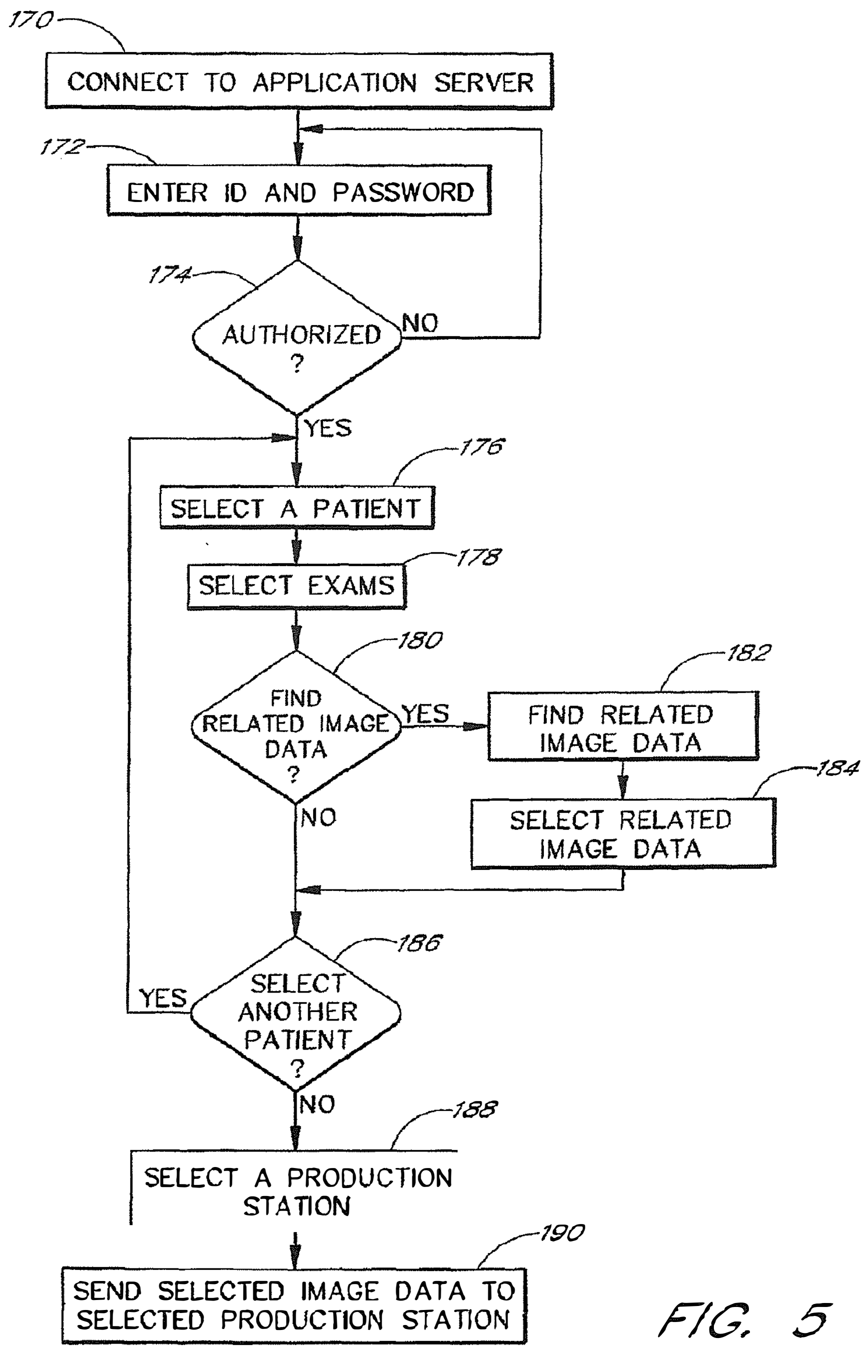

170
CONNECT TO APPLICATION SERVER
172
ENTER ID AND PASSWORD
174
AUTHORIZED ?
NO
YES
176
SELECT A PATIENT
178
SELECT EXAMS
180
FIND RELATED IMAGE DATA ?
YES
182
FIND RELATED IMAGE DATA
184
SELECT RELATED IMAGE DATA
NO
186
SELECT ANOTHER PATIENT ?
YES
NO
188
SELECT A PRODUCTION STATION
190
SEND SELECTED IMAGE DATA TO SELECTED PRODUCTION STATION

FIG. 5

SYSTEM AND METHOD FOR PRODUCING MEDICAL IMAGE DATA ONTO PORTABLE DIGITAL RECORDING MEDIA

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 11/942,630, filed on Nov. 19, 2007, which is a continuation of U.S. patent application Ser. No. 09/761,795, filed on Jan. 17, 2001, now U.S. Pat. No. 7,302,164, issued Nov. 27, 2007, which claims priority to U.S. Provisional Patent Application 60/181,985, filed on Feb. 11, 2000. The entire disclosures of these applications are hereby incorporated by reference herein in their entirety.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to a system and method for the production of medical image data on portable digital recording media such as compact discs. More particularly, it relates to a system and method for receiving medical image data, processing medical image data, and transmitting medical image data to be recorded on a portable digital recording medium.

2. Description of the Related Art

Since the invention of the x-ray film, film has been the predominant multipurpose medium for the acquisition, storage, and distribution of medical images. However, the storage and distribution of film often requires considerable expenses in labor and storage space.

Today's modern hospitals utilize computer-aided imaging devices such as Computed Tomography (CT), Digital Subtracted Angiography, and Magnetic Resonance Imaging (MRI). These digital devices can generate hundreds of images in a matter of seconds. Many hospitals require these images to be printed on film for storage and distribution. To print complete sets of medical images from these digital devices, the cost in film material, storage space, and management efforts is often very high.

Some radiology departments have installed digital image storage and management systems known as PACS (Picture Archive Communication Systems). PACS are capable of storing a large amount of medical image data in digital form. PACS are made by manufacturers including GE, Siemens, and Fuji.

To ease the communication of data, the DICOM (Digital Imaging and Communications in Medicine) standard was developed by ACR-NEMA (American College of Radiology-National Electrical Manufacturer's Association) for communication between medical imaging devices and PACS. In addition to the examined images, patient demographics, and exam information such as patient name, patient age, exam number, exam modality, exam machine name, and exam date can also be stored and retrieved in DICOM compatible data format. A DICOM file stores patient and exam information in the header of the file, followed by the exam images. PACS store medical image data in DICOM format.

Digital medical image data can be stored on PACS and distributed using the Internet. However, many physicians' offices do not have the bandwidth suitable for fast download of medical image data. The concerns for medical data privacy and Internet security further reduce the desirability of Internet distribution.

SUMMARY OF THE INVENTION

The claimed system allows for digital medical image data to be produced on a portable digital recording medium such as a CD. A CD containing the medical image data can be distributed to physicians, hospitals, patients, insurance companies, etc. One embodiment of the claimed system allows for medical image data to be placed on a CD along with a viewing program, so that a user can use any computer compatible with the CD to view the medical image data on the CD. One embodiment of the claimed system allows for searching medical exam data that are related and placing such data on the same CD.

One embodiment of the claimed system comprises a receiving module configured to receive medical image data, a processing module configured to process the received medical image data, and an output module configured to transmit the processed medical image data to a production station configured to produce the transmitted medical image data on portable digital recording medium, such as a CD. In one embodiment, the output module transmits a viewing program configured to view medical image data to the production station so that the viewing program is produced on the same CD as the medical image data. In another embodiment, the CD already contains the viewing program before the medical image data is transmitted to the CD production station.

In one embodiment of the claimed system, the processing module is configured to create and store audit information of the portable digital recording medium produced by the production station.

In another embodiment of the claimed system, the processing module is configured to identify the originating image input device of the received medical image data, and determine, on the basis of the originating image input device, whether to transmit the received medical image data to a production station. The processing module also selects, on the basis of the originating image input device, one of multiple production stations as the target production station.

Yet another embodiment of the claimed system is configured to retrieve medical image data that are related to the received medical image data, and transmit the retrieved related image data to the production station. In one embodiment, exam images of the same patient are considered related. In another embodiment, exam images of the same patient and the same modality are considered related. For example, two x-ray exams on the left hand of the same patient are considered related. In yet another embodiment, exam images of the same patient, the same modality and taken within a specified date range are considered related. For example, two x-ray exams on the left hand of the same patient taken within a two-month period are considered related. A hospital may also determine other scenarios of relatedness.

One claimed method comprises the steps of connecting a browsing terminal to a computer database configured to store medical image data, selecting medical image data from medical image data stored on the database, and recording the selected medical image data on portable digital recording medium. In one embodiment, the claimed method also comprises a step of recording a viewing program configured to view medical image data on the portable digital recording medium.

One embodiment of the claimed method further comprises the steps of finding and retrieving medical image data that are

related to the selected medical image data, and recording related image data to portable digital recording medium.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** illustrates one embodiment of an image production system comprising an application server and portable digital recording medium production stations.

FIG. **2** illustrates sample records of one embodiment of an image input device profile table.

FIG. **3** illustrates a process of receiving image data from image server, processing received image data, and transmitting such data to the production station. This process also retrieves and transmits related image data for production.

FIG. **4** illustrates a process of a user selecting and ordering the production of image data stored on the application server.

FIG. **5** illustrates a process of a user selecting and ordering the production of image data stored on the application server, with the option of selecting and ordering the production of related image data.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. **1** illustrates one embodiment of an image production system **100** comprising an application server **110** and one or more portable digital recording medium production stations **300**A, **300**B and **300**C. In the preferred embodiment, the production stations **300**A, **300**B and **300**C are CD (Compact Disc) production stations. Digital portable recording medium comprises CDs and DVDs (Digital Versatile Disc or Digital Video Disc). CDs may comprise CD-ROM (Compact Disc Read Only Memory), CD-R (Compact Disc Recordable), and CD-RW (Compact Disc Recordable and Writable). DVDs may comprise DVD-ROM (DVD Read Only Memory), DVD-R (DVD Recordable) and DVD-RAM (a standard for DVDs that can be read and written many times). Thus, although the following description refers primarily to CDs, those of ordinary skill in the art will understand that any suitable portable digital recording medium can be substituted for CDs.

The application server **110** is connected to one or more physician browsing terminals **400**A, **400**B and **400**C through a computer network **600**. Each physician browsing terminal **400**A, **400**B or **400**C comprises a browsing program such as Internet Explorer or Netscape Communicator. Physicians or their assistants launch the browsing program to access the application server **110** through the network **600** in order to select medical image data stored on the application server database **114** to be produced by a production station **300**A, **300**B or **300**C. In the preferred embodiment, the physician browsing terminals **400**A, **400**B and **400**C are connected to the application server through an Intranet. One embodiment of the Intranet utilizes TCP/IP network protocol. The Intranet can connect one radiology department, multiple departments within a hospital, or multiple hospitals. In another embodiment the browsing terminals **400**A, **400**B and **400**C are connected to the application server **110** through the Internet.

Still referring to FIG. **1**, the application server **110** is also connected to an image server **200**. The image server **200** is further connected to image input devices such as PACS **204**, MRI machines **206**, CT-scan machines **208**, ultrasound machines **210**, etc. In the preferred embodiment, the image server **200** is a DICOM image server configured to receive and store medical image data in DICOM format. In operation, the image server **200** receives medical image data from image input devices such as PACS **204**, MRI machines **206**, CT-scan machines **208** and ultrasound machines **210** and stores such image data in the image server database **202**. A high-resolution image scanner **500** is also connected to the image server **200**, so that medical image data stored on film can be scanned on the image scanner **500**, transmitted to the image server **200** and stored in the image server database **202**. In one embodiment, the image scanner **500** also converts the scanned image to DICOM format. The application server **110** receives input image data from the image server database **202**, processes the received image data, and sends the image data to one of the production stations **300**A, **300**B or **300**C to produce CDs.

The application server **110** comprises a viewing program **112**, an application server database **114** that stores image data received from the image server **200**, a production history database **116** that stores audit records on each CD produced, a display terminal **118** for programming and operating the application server **110** by a programmer or physician, and an image input device profile table **120**.

Still referring to FIG. **1**, the viewing program **112** is configured to allow users to read and manipulate medical image data. The viewing program **112** comprises multiple image manipulation functions, such as rotating images, zooming in and zooming out, measuring the distance between two points, etc. The viewing program **112** also allows users to read the patient demographics and exam information associated with the image data. The viewing program **112** used in the preferred embodiment is produced by eFilm Medical Inc. located in Toronto, Canada. The viewing program **112** used in the preferred embodiment is an abbreviated version with fewer functions and takes less storage space, in order to maximize the storage space for image data on a CD. The image server **200** used in the preferred embodiment is also made by eFilm Medical Inc.

The CD production stations **300**A, **300**B and **300**C in the preferred embodiment are produced by Rimage Corporation in Edina, Minn. Details about the Rimage CD production stations can be found in U.S. Pat. Nos. 5,542,768, 5,734,629, 5,914,918, 5,946,276, and 6,041,703, which are incorporated herein by reference in their entirety.

The application server **110** in the preferred embodiment runs on a personal computer running a 400 MHz Celeron or Pentium II/III chip, with Windows 98 or NT as the operating system.

FIG. **2** illustrates sample records of one embodiment of an image input device profile table **120**. The image input device profile table **120** contains a profile record for each image input device. Each image input device's profile record comprises: (1) an "auto-produce" logical field **250** indicating whether medical image data from this image input device should be produced on CD automatically by the image production system **100**, (2) a "target production station" field **252** identifying one of the production stations **300**A, **300**B or **300**C on which medical image data is to be produced, and (3) a "related data storage" **254** field identifying the medical image data storage units in which to search for the related image data. A medical image data storage unit is a storage unit that stores medical image data and is connected to the application server **110**. In one embodiment, a medical image data storage unit is connected to the application server **110** through the image server **200**. In the preferred embodiment, PACS **204** is such a medical image data storage unit.

In FIG. **2**, the sample profile table **120** contains profile records for MRI Machine I, MRI Machine II, and Ultrasound Machine I. For MRI Machine I, the "auto-produce" field **250** contains a "yes" value, directing the image production system **100** to automatically produce image data originating from MRI Machine I on portable digital recording medium. Its

"target production station" field **252** contains a "Production Station A" value, directing the image production system **100** to produce image data originating from MRI Machine I on production station A. Its "related data storage" field **254** is "PACS I", directing the image production system **100** to retrieve related medical image data from PACS I. For MRI Machine II, the "auto-produce" field **250** is "no", directing the image production system **100** to not automatically produce image data originating from MRI Machine II on portable digital recording medium. Since image data from MRI Machine II will not be automatically produced, the "target production station" field **252** and the "related data storage" field **254** are irrelevant. For Ultrasound Machine I, the "auto-produce" field **250** is "yes", and its "target production" field **252** is "Production Station B". Its "related data storage" field **254** contains a value of "PACS I, PACS II", directing the image production system **100** to search PACS I and PACS II for related medical image data.

FIG. **3** illustrates a process of the application server **110** receiving image data from the image server **200**, processing the received image data, and transmitting such data to the production station **300**A, **300**B or **300**C. The application server **110** continuously monitors the image server database **202** in step **122**. In one embodiment, the application server continuously "pings" the network address corresponding to the image server **200** on the network that connects the application server **110** with the image server **200**.

Still referring to FIG. **3**, the application server **110** determines if the image server database **202** is changing, in step **124**. In the preferred embodiment, the application server **110** makes that determination by detecting whether the image server database **202** is increasing in size. If there is no change in the image server database **202**, then the application server **110** returns to step **122** to continue monitoring. If there is change in the image server database **202**, then the application server **110** proceeds to step **126** and time-stamps the moment that the change started. The application server **110** then proceeds to step **128** and waits for an interval, typically 35 to 65 seconds. After the interval, the application server **110** checks whether the image server database **202** is still changing, in step **130**. If the image server database **202** is still changing then the application server **110** returns to step **128** to wait for another interval. If the image server database **202** is no longer changing, then the application server **110** proceeds to step **132** and copies the data changed since the time-stamped moment. This changed data is copied from the image server database **202** to the application server database **114**.

The application server **110** proceeds to step **134** and finds the input image device name or identification number from the newly received image data. In the preferred embodiment, image data from the image server database **202** are stored in DICOM format, and the input image device name or identification number is stored in the header of the DICOM format image data file. The input image device name/ID indicates the origin of the newly received data. The application server **110** proceeds to step **136** and uses the found input image device name/ID to find a corresponding profile record in the image input device profile table **120**. If the profile record has an "auto-produce" field **250** with a "no" value, the application server **110** returns from step **138** to step **122** to continue monitoring the image server database **202**. If the "auto-produce" field **250** contains a "yes" value, the application server **110** proceeds from step **138** to step **140**, and determines the target production station **300**A, **300**B or **300**C from the "target production station" field **252** of the profile record. In step **140**, the application server **110** also determines the value in the "related data storage" field **254** of the profile record.

Still referring to FIG. **3**, in step **142**, the application server **110** sends a copy of the newly received data, along with a copy of the viewing program **112**, to the target production station **300**A, **300**B or **300**C identified in step **140**. With the viewing program attached, the image data on each CD produced by the target production station **300**A, **300**B or **300**C can be viewed on any computer that accepts the CD, regardless of whether that computer has its own viewing program installed. In one embodiment, the data received in step **132** is stored in the application server database **114** before it is transmitted to the target production station **300**A, **300**B or **300**C in step **142**. In another embodiment, the application server **110** transmits the data received in step **132** to the target production station **300**A, **300**B or **300**C, without storing a copy of the data in the application server database **114**.

In one embodiment, the application server **110** does not send a copy of the viewing program **112** to the target production station during step **142**. Rather, the application server **110** sends a copy of the received medical image data to the production station **300**A, **300**B or **300**C to be recorded on pre-burned CDs. Each pre-burned CD contains a viewing program already recorded onto the CD before step **142**.

In step **142**, the application server **110** also sends configuration data to the target production station **300**A, **300**B or **300**C. The configuration data comprises a label-printing file comprising the specification for printing labels on top of the CDs, and a "number of copies" value indicating the number of copies of CDs to be produced. A typical specification in the label-printing file may specify information such as patient name, exam modality, hospital name, physician name, production date, etc. to be printed by the target productionstation as a label on the top of each CD produced.

Still referring to FIG. **3**, in step **143**, the application server **110** searches the application server database **114** for image data related to the newly received data. The application server **110** then searches the PACS systems identified in the "related data storage" field **254** in step **140** for data related to the newly received data. Some PACS systems each comprise a primary image data storage and an archive image data storage, and the application server **110** searches both the primary image data storage and the archive image data storage on these PACS systems. The application server **110** is connected to the PACS systems through the image server **200**. The application server **110** retrieves found related data from the PACS systems and stores a copy of such found related data in the application server database **114**. The application server **110** sends a copy of related data that are found from the application server database **114** or the PACS systems to the target production station **300**A, **300**B or **300**C. The medical image data originally received in step **132** and the related medical image data are produced by the target production station **300**A, **300**B or **300**C on the same CDs for comparative study.

For each CD to be produced, the application server **110** adds one audit record to the production history database **116** in step **144**. The new audit record comprises the identification number of the CD and other relevant information about the CD, such as the physician who requested the production (if any), and the names of the patients whose exam images are on that CD.

Steps **142**, **143** and **144** may be executed immediately before, concurrent with, or immediately after one another.

The target production station **300**A, **300**B or **300**C produces the CDs containing the medical image data and the viewing program sent to it, and prints a label on top of every CD, corresponding to the specification in the label-printing file. The number of CDs produced corresponds to the "number of copies" number sent by the application server **110** in

step **142**. When the target production station has produced the CDs, the production station returns a "completed" signal to the application server **110**. The application server **110** waits for this signal in step **146**.

Still referring to FIG. **3**, in step **148**, the application server **110** updates the audit records in the production history database **116** that were created in step **144**. For each CD produced, the application **110** server updates the date and time of production for that CD's audit record. The application server **110** also updates the status value for that CD's audit storage record from "processing" to "successful". The application server **110** then continues monitoring the image server database **202** as in step **122**.

FIG. **4** illustrates a process of a user selecting and ordering the production of image data stored on the application server **110**. A user, typically a physician or physician's assistant, accesses the application server database **114** from a browsing terminal **400**A, **400**B or **400**C connected to a network **600**. In one embodiment, the user launches a browser such as Microsoft Internet Explorer or Netscape Communicator, and specifies a network address corresponding to the application server **110**, in step **150**. In another embodiment, the user clicks a pre-defined icon that directly launches a browser connecting to the application server **110**. The application server **110** prompts the user to enter a password or an identification name coupled with a password, in step **152**. The application server **110** checks if the entered identification/password is authorized in step **154**. If the entered identification/password is not authorized the user is returned to step **152** to re-enter the identification/password, or disconnected from the application server **110**. If the entered identification/password is authorized then the user is allowed access to the application server database **114** and the application server **110** proceeds to step **156**.

Still referring to FIG. **4**, in step **156** the user is prompted to select a patient from a list of patients with exam images in the application server database **114**. The user is then shown a list of the selected patient's exams, and is prompted to select one or more exams of that patient, in step **158**. When the user indicates that he/she has completed selecting all exams for that patient, the user is asked in step **160** whether to select another patient from the list of patients. If the user answers "yes", the user is returned to step **156** to select another patient. If the user answers "no", the user proceeds to step **162**.

In another embodiment, when a user selects a patient, all exams belonging to that patient will be automatically selected without prompting for user selection. In yet another embodiment, the user is not prompted to select patients, but is only prompted to select exams from a list of all exams for all patients contained in the application server database **114**.

When the user indicates that he/she has completed selecting, the user is prompted to select a production station from a list of production stations **300**A, **300**B and **300**C in step **162**. The user is also prompted to enter additional label text to be printed as labels on the CDs to be produced, to supplement the text printed according to the specification of the label-printing file. The user can advantageously select the production station located closest to his/her office. In one embodiment, only one production station is connected to the application server **110**, and the lone production station will be the selected production station without prompting for user selection.

In one embodiment, the user is also prompted to select the number of copies of CDs to be produced. In another embodiment, the number of copies is set at one without prompting for user direction. As described above in connection with FIG. **3**, in step **164**, the application server **110** sends a copy of the image data of the selected exams for the selected patients to the selected production station, along with a copy of the viewing program **112**, and configuration data comprising a label-printing file, additional label text, and a number indicating the number of copies of CDs to be produced. The production station **300**A, **300**B or **300**C then produces one or more CDs containing the selected exams for the selected patients and the viewing program, with labels printed on top of the CDs according to the specification in the label-printing file and the user-entered additional label text.

In another embodiment, a user accesses the application server database **114** not from a browsing terminal **400**A, **400**B or **400**C, but directly from the display terminal **118**. In this embodiment the user directly proceeds from step **152**. In this embodiment the user is typically a programmer or operator of the image production system **100**.

FIG. **5** illustrates a process of a user selecting and ordering the production of image data stored on the application server **110**, with the additional option of selecting and ordering the production of related data for comparative study. As described above in connection with FIG. **4**, a user connects to the application server **110** from a browsing terminal **400**A, **400**B or **400**C in step **170**. The user enters identification information and a password in step **172**. Step **174** determines whether the user is authorized to access the application server database **114**. If authorized, the user is prompted to select a patient in step **176**, and selects exams of the selected patient in step **178**. The user is then asked in step **180** if he/she desires to find related data of that patient for comparative study.

If the user answers yes, the application server **110** then searches for related data. The application server **110** finds the image input device profile table **120** profile record corresponding to the image input device from which the selected data originates, identifies the list of PACS systems stored in the "related data storage" field **254**, and searches these PACS systems for related data. In another embodiment, once the user has selected a patient/exam combination, the application server **110** automatically searches for related data without asking for user direction. In this embodiment, the application server **110** alerts the user if related data are found. In one embodiment, the application server **110** also searches the application server database **114** for related medical image data.

Still referring to FIG. **5**, the user is then prompted to select all or some of the related data from the list of found related data for production, in step **184**. In another embodiment, all found related data are automatically selected by the application server **110** for production, without prompting for user selection.

The user is then prompted to select another patient in step **186**. After the user has completed selecting all patients, the user is prompted to select a CD production station **300**A, **300**B or **300**C in step **188**. The user is also prompted to enter additional label text. In step **190**, the application server **110** then sends a copy of the original and selected related data, along with a copy of the viewing program **112**, a number indicating the number of copies to be produced, additional label text, and a label-printing file to the selected production station **300**A, **300**B or **300**C for production.

The above paragraphs describe the application server **110** with one database **114** for image data storage. In another embodiment, the application server **110** includes two databases for image data storage: a new data database and a storage data database. The new data database stores only the most recent batch of new data just received from the image server **200**. After the data in the new data database is sent to a production station **300**A, **300**B or **300**C, the application

server **110** erases data in the new data database. The storage data database stores all data that has ever been received from the image server database **202**. In the processes described by FIG. **4** and FIG. **5**, a user selects images for production from the storage data database.

Several modules are described in the specification and the claims. The modules may advantageously be configured to reside on an addressable storage medium and configured to execute on one or more processors. The modules may include, but are not limited to, software or hardware components that perform certain tasks. Thus, a module may include, for example, object-oriented software components, class components, processes methods, functions, attributes, procedures, subroutines, segments of program code, drivers, firmware, microcode, circuitry, data, databases, data structures, tables, arrays, and variables. Modules may be integrated into a smaller number of modules. One module may also be separated into multiple modules.

Although the foregoing has been a description and illustration of specific embodiments of the invention, various modifications and changes can be made thereto by persons skilled in the art, without departing from the scope and spirit of the invention as defined by the following claims.

What is claimed is:

1. A system comprising:

a medical image server configured to receive medical image data generated by one or more imaging modalities, the medical image data being formatted in a standard medical imaging format;

a database configured to store medical image data generated by the one or more imaging modalities;

a plurality of browsing terminals configured to receive a user selection that defines selected medical image data for a patient;

a search module configured to automatically search the database for related data based on the user selection; and

a production station that is configured to record all of the following onto a data storage medium:

the selected medical image data for the patient, recorded in the standard medical imaging format, the related data, and a viewing program that is configured to allow viewing of medical image data that is recorded onto the data storage medium by a general purpose computer that is not specifically configured with medical imaging software for viewing of medical images formatted in the standard medical imaging format.

2. The system of claim **1**, further comprising a configuration data module configured to allow a user to input identifying information relating to the selected medical image data.

3. The system of claim **2**, wherein the production station is configured to produce a label for the data storage medium, the label containing the identifying information.

4. The system of claim **1**, further comprising an audit module that is configured to automatically provide an auditable trail of the selected medical image data.

5. The system of claim **4**, wherein the auditable trail of the selected medical image data includes a record of when the selected medial image data and the related medical image data were recorded onto the data storage medium.

6. The system of claim **4**, wherein the auditable trail of the selected medical image data includes identifying information corresponding to the production station used to record the selected medial image data and the related data onto the data storage medium.

7. The system of claim **1**, wherein the data storage medium is an optical disk.

8. A method of recording medical image data and related data onto a data storage medium, the method comprising:

receiving medical image data from one or more imaging modalities, the received medical image data being formatted in a standard medical imaging format;

storing the received medical image data in a database;

receiving a user selection that defines selected medical image data for a patient;

automatically searching the database for related data based on the user selection;

recording the selected medical image data for the patient and the related data onto a data storage medium using a production station, the selected medical image data being recorded on the data storage medium in the standard medical imaging format;

recording a viewing program onto the data storage medium using the production station, the viewing program being configured to allow viewing of medical image data stored on the data storage medium on a general purpose computer that is not specifically configured with medical imaging software for viewing of medical images formatted in the standard medical imaging format; and

labeling the data storage medium with a label that includes identifying information associated with the selected medical image data.

9. The method of claim **8**, wherein the user interface is further configured to collect the identifying information from the user.

10. The method of claim **8**, further comprising generating an auditable trail of the selected medical image data, wherein the auditable trail includes a record of when the selected medial image data and the related medical image data were recorded onto the data storage medium.

11. The method of claim **8**, wherein receiving a user selection comprises selecting one or more patients from a list of patients having medical image data stored in the database.

12. The method of claim **8**, wherein the plurality of imaging modalities includes an image scanner configured to generate medical image data in a DICOM-compatible format from film.

13. The method of claim **8**, wherein the data storage medium is an optical disk.

14. The method of claim **8**, wherein recording the selected medical image data and the related data further comprises selecting a production station from a plurality of production stations that are connected to the database via a computer network.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 7,783,174 B2
APPLICATION NO. : 12/484100
DATED : August 24, 2010
INVENTOR(S) : Wright et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 2, Page 3 (Item 56), Line 17, under Other Publications, change "BringharnRAD:" to --BringhamRAD:--.

In Column 2, Page 3 (Item 56), Line 37, under Other Publications, change "Johnson," to --Johnston,--.

In Column 2, Page 4 (Item 56), Line 43, under Other Publications, change "at al.," to --et al.,--.

In Column 1, Page 5 (Item 56), Line 42, under Other Publications, change "EurIPACS," to --EuroPACS,--.

In Column 2, Page 5 (Item 56), Line 14, under Other Publications, change "DeJamette" to --DeJarnette--.

In Column 2, Page 5 (Item 56), Line 16, under Other Publications, change "Entwickiung" to --Entwicklung--.

In Column 1, Page 6 (Item 56), Line 58, under Other Publications, change "Acculmage" to --Accuimage--.

In Column 1, Page 7 (Item 56), Line 67, under Other Publications, change "HIPPA"," to --HIPAA",--.

In Column 2, Page 7 (Item 56), Line 1, under Other Publications, change "et all," to --et al.,--.

In Column 1, Page 10 (Item 56), Line 57, under Other Publications, change "Mitre" to --Mitra--.

In Column 1, Page 10 (Item 56), Line 63, under Other Publications, change "Mitre" to --Mitra--.

In Column 2, Page 10 (Item 56), Line 38, under Other Publications, change "radiographics.rsnajnls.orq" to --radiographics.rsnajnls.org--.

Signed and Sealed this
Twenty-ninth Day of March, 2011

David J. Kappos

David J. Kappos
Director of the United States Patent and Trademark Office

In Column 1, Page 11 (Item 56), Line 36, under Other Publications, change "“Medlmage" to --“Medimage--.

In Column 1, Page 11 (Item 56), Line 44, under Other Publications, change "Desecription" to --Description--.

In Column 2, Page 11 (Item 56), Line 38, under Other Publications, change "Medlmage" to --Medimage--.

In Column 2, Page 11 (Item 56), Line 43, under Other Publications, change "MBA,," to --MBA.,--.

In Column 1, Page 12 (Item 56), Line 15, under Other Publications, change "Servise" to --Service--.

In Column 1, Page 12 (Item 56), Line 22, under Other Publications, change "Mitre" to --Mitra--.

In Column 1, Page 12 (Item 56), Line 28, under Other Publications, change "Mitre" to --Mitra--.

In Column 1, Page 12 (Item 56), Line 37, under Other Publications, change "Mitre" to --Mitra--.

In Column 1, Page 12 (Item 56), Line 45, under Other Publications, change "Mitre" to --Mitra--.

In Column 2, Page 12 (Item 56), Line 55, under Other Publications, change "Perfectlmage" to --Perfectimage--.

In Column 1, Page 13 (Item 56), Line 44, under Other Publications, change "Mitre" to --Mitra--.

In Column 2, Page 13 (Item 56), Line 48, under Other Publications, change "BaSed" to --Based--.

In Column 2, Page 14 (Item 56), Line 46, under Other Publications, change "Medial" to --Medical--.

In Column 1, Page 15 (Item 56), Line 4, under Other Publications, change "Gmbh," to --GmbH,--.

In Column 1, Page 15 (Item 56), Line 21, under Other Publications, change "Medlmage" to --Medimage--.

In Column 1, Page 15 (Item 56), Line 32, under Other Publications, change "Advertist" to --Adventist--.

In Column 1, Page 15 (Item 56), Line 36, under Other Publications, change "Medlmage" to --Medimage--.

CERTIFICATE OF CORRECTION (continued)
U.S. Pat. No. 7,783,174 B2

In Column 1, Page 15 (Item 56), Line 38, under Other Publications, change "Medlmage" to --Medimage--.

In Column 1, Page 15 (Item 56), Line 40, under Other Publications, change "Medlmage" to --Medimage--.

In Column 10, Line 1, in Claim 5, change "medial" to --medical--.

In Column 10, Line 6, in Claim 6, change "medial" to --medical--.

In Column 10, Line 41, in Claim 10, change "medial" to --medical--.

EXPERT REPORT OF STEVEN HORII, M.D.

In the Matter of DatCard Systems, Inc. v. PacsGear, Inc.

United States District Court For The Central District Of California

Case No.: SACV10-1288 DOC (VBKx)

[OUTSIDE COUNSEL ONLY – PURSUANT TO PROTECTIVE ORDER]

ABSTRACT

I have been engaged by counsel for Defendant PACSGEAR to offer my opinions on the validity of plaintiff DatCard's patents in suit. These patents relate to the electronic transfer of medical images and recording the images onto CDs.

The patents discuss Picture Archiving and Communications Systems, commonly called PACS. PACS are systems used for the digital transmission and storage of medical images, e.g., MRI's, CT Scans, Ultrasound. PACS are the means by which images created by the device are transmitted to a database, where they can be accessed by treating physicians' workstations and copied for distribution to those who need them, such as patients and referring physicians. Typical PACS systems conform to what the patents refer to as "a standard medical imaging format." In practice, that format typically is the DICOM Standard. DICOM consists of a detailed and comprehensive set of protocols that have been adopted worldwide. I have devoted much of my career over the past three decades to the development of DICOM.

DatCard's patents claim a simple DICOM-conforming medical image storage, transfer and copy system. Nearly all its features were built into systems conforming to the DICOM Standard more than five years before the first patent was applied for. All of the features claimed were well known in the literature and in practice before DatCard's claimed inventions. For

Exhibit A

III. HISTORICAL BACKGROUND

A. The Use Of Film And Film Libraries

For close to a century, radiologists used film to capture, view, transfer and store the images. As Dr. Harry Fischer (Fischer 1982) teaches, film libraries were established to provide films to the physicians and other personnel caring for patients. If patients were transferred to other facilities, or if they needed their films for a second opinion, film libraries also provided the films (or copies) to patients for their patient folders.

Because the film was the sole image record of the examination unless it was copied and due to privacy concerns, means were established that paralleled the functions in a literary library. Films had to be signed out and a record kept of the borrower, information about the images (e.g., date, content, modality), the hospital person facilitating/authorizing the check out and when they were taken. The filmless system was broadly modeled to digitally emulate the film-based filing system. Seshadri (1992) provides a more thorough discussion of making the transition from film jackets to digitally based systems. (**Exhibit 6B**).

The organization of film libraries included the creation of film jackets that held a number of folders. The jacket served as a master folder and had space on the outside to record what folders were included. The folders themselves were typically organized by the type of image or by imaging technique and would contain subfolders if the patient had more than one of that particular imaging study along with any diagnostic reports.

B. Early Filmless Image Transmission

Early digitized medical systems were designed for communication of radiological images (e.g. University of Pennsylvania system discussed in Seshadri et al article 1990) within hospitals, for the diagnosis and monitoring of a patient's condition. These Picture Archiving and

Communication Systems were the early versions of the modern day PACS. However, because such PACS were hospital-based, most physicians outside the hospital did not have electronic access to patient images. For this reason, an early method of distributing images from PACS to non-hospital doctors was to print the images directly from the modality or other storage device on film and deliver them for viewing on the traditional lightbox.

The progress and development of digital media came from the consumer electronics industry. Vinyl analog records were replaced by digital Compact Discs (CD). Makers of personal computers took advantage of the large storage capacity of CDs and began to advocate for using the recordable CD for storage and distribution of digital information. Other medical specialties that used imaging, particularly cardiology, also made the transition to digital imaging. Conventional cardiac x-ray imaging used 35mm motion picture (cine) film, so cardiology film libraries contained many canisters of such films.

Digital imaging provided an opportunity to replace such film with electronic storage, but the cardiologist still had a requirement to view the dynamic imaging that the cine film provided. While video recording was one solution, analog video playback did not handle changes in playback speed or direction well. A digital media based solution was very much desired by the cardiology community. Because systems were essentially created ad hoc at the hospital level with the assistance of large OEMs, like General Electric, Philips and Siemens, there was no uniformity between one modality and/or PACS system and another, so the benefits of universal filmless transmittal of images could not then be realized.

In 2007, the Society for Imaging Informatics in Medicine (SIIM) working with the American Registry of Radiologic Technologists (ARRT) established the independent American Board of Imaging Informatics (ABII). The ABII certifies "Imaging Informatics Professionals," called CIIP's. CIIPs have come from both the radiologic technology and computer science/information technology areas. I was on the Committee that drafted the initial CIIP examination.

Although the CIIP program wasn't around at the time of the invention, in my opinion, the ordinary person of skill in the art would be a person with a background commensurate with that of a CIIP with five years experience in the design, use and implementation of PACS, or a radiologist or medical computer networking specialist with equivalent experience.[1] *This profile is quite similar to that proposed by Ken Wright, the inventor, at page 233 of his deposition.* **Exhibit 3.**

It will shorten this analysis considerably if we recognize that most of claim limitations (e.g., send, query/retrieve, record onto a CD, etc…) would be understood by the hypothetical skilled person reading the patent to be present in essentially any DICOM-conforming PACS system.

B. The Architecture Of DICOM Conforming PACS Systems As It Relates To Claim Construction

Any person of ordinary skill in the art as of the critical date would correctly understand that the basic architecture of DICOM-based systems is built into all the claims. The premise for this assumption is that all of the claims specify that the "medical image data" be "formatted in a standard medical imaging format." See, e.g. claim 9 of the '164 patent, col. 10 ll. 42-67. The

[1] As discussed below, the actual programming covered by the '422 Patent would require additional computer programming experience.

patent specification refers to DICOM as the format in the description of the best mode (Col. 3, ll. 55-56) and as of the critical date, there was no other "standard medical imaging format" that supported the variety of imaging methods that DICOM does and there is none today.

The essential function of DICOM is the communication of medical images. The Standard defines many elements needed for a database and also has low-level functions (Query and Retrieve) for locating a particular DICOM image on a DICOM-conformant device that stores such images (i.e., a database).[2] A key task of radiologists is to compare a current study with a prior one or a study from a different type of modality to determine, for example, if disease is getting worse or improving. Any PACS must support the operations of having a record of a patient's imaging studies and knowing where they are stored.

Even though computer systems, networks, and storage systems are fast, digital images are large in terms of digital data. A single CT examination may consist of over a thousand images. Comparing that with the prior study means displaying the current thousand images and retrieving the correct previous thousand images from storage. Without a database, an exhaustive search of a potentially huge amount of information would have to be undertaken.

Part 11 of DICOM defines Media Application Profiles. These describe how specific types of imaging studies are stored on media. These profiles define the elements needed to store DICOM images. Part 12 of DICOM defines the actual media formats and media to be used with the Application Profiles of Part 11. To completely define DICOM conformant media, an Application Profile is used with a particular medium (e.g., CD-R) and the particulars of file

[2] The DICOM Standard does not specifically define a database. During my tenure as Co-Chairman of the DICOM Standards Committee, I recall that there was considerable discussion regarding this idea. In the end, it was thought better not to define a database as doing so might restrict innovation or unfairly advantage a vendor who used the particular database chosen for the Standard.

organization on that medium defined in Part 12. The Standard does, however, illustrate the potential use of exchange media, essentially serving as an alternative to a DICOM network connection.

The first large-scale implementation of DICOM Parts 11 and 12 was the aforementioned work by the American College of Cardiology (Elion 1995). This embodiment combined the "Basic Cardiac X-Ray Angiographic Application Profile" of DICOM Part 11 with the "120mm CD-R Medium" specification of DICOM Part 12. This was a demonstration that the Standard could be implemented and the resulting CDs readable by multiple vendors. As discussed above, the next year the ACC included viewing software on a sample CD to enable users to view the DICOM images on any Windows-based computer.

C. Claim Construction of the '164 Patent

1. Claim 9

The first disputed claim of the earliest patent issued is claim 9 of U.S. Patent No. 7,302164. I have numbered its five elements as follows:

> "9. A system comprising:
> [1] a medical image server configured to receive medical image data that is generated by a plurality of imaging modalities, the medical image data being formatted in a standard medical imaging format used by specialized computers configured for viewing medical images;
> [2] a database configured to store medical image data generated by the plurality of imaging modalities;
> [3] a plurality of browsing terminals configured to receive a user selection that defines selected medical image data;
> [4] a search module configured to search the database for related medical image data that is related to the selected medical image data; and
> [5] a production station that is configured to record all of the following onto a single, portable digital data storage device that is removable from the production station: the selected medical image data, recorded in the standard medical imaging format, the related medical image data, recorded in the standard medical imaging format, and a viewing program that is configured to allow viewing of the selected and the related medical image data that is recorded onto the data storage device on widely accessible

First, at page 17, he refers to a "database" on the local hard drive of the MediaWriter where medical images selected for copying are stored during the burning to CD process. This "database" on MediaWriter's local hard drive is not searchable, as required by the claim, and merely acts as a non-searchable depository for medical images (i.e., a buffer) that have been searched for and retrieved from the PACS or sent directly by a modality in the case of Auto Burn. In my opinion, this is not a "database", as discussed above. Based on a discussion with Brian Cavanaugh of PacsGear, I learned that the decision not to allow a user to search for medical images on the hard drive was intentional. This was done because medical images stored on PACS may have changed (i.e., annotated, updated, etc.) since moved to the MediaWriter hard disk; the intention of the MediaWriter is to require a new search of the remote PACS database to prevent an incomplete or outdated study from being recorded to CDs. The reference to this hard drive location in the MediaWriter's Software Requirements Specification as a "database" is an in-artful use of the term. As the term "database" in the patent's specification refers to a storage device that is searched (e.g., Col.2 ll. 54-58), a location on the local hard drive which only stores medical image data is not a database, as properly construed by one skilled in the art. As a result, this storage location cannot be the "database" referred to in the claim.

Next, again at page 17, Dr. Rowberg contends that PACS archives and imaging modalities include a database configured to store medical image data. Although this is true, these components are not part of the MediaWriter and customers determine how or if they use these components. The '164 Patent (Col. 4, 32-33) describes the image server (200-Figure 1) as being supplied by eFilm and is separate from any database on the PACS or imaging equipment. It is also separate and distinct from the application server and the application server database (Figure 1). The MediaWriter does not have an "image server" , as shown in the patent, as the

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SOUTHERN DIVISION

DATCARD SYSTEMS, INC., a California corporation, Plaintiff, v. PACSGEAR, INC., a California corporation, Defendant. AND RELATED COUNTERCLAIM	Civil Action No. SACV10-1288 DOC (VBKx) **INITIAL EXPERT REPORT OF DR. ALAN ROWBERG, M.D.**

<u>CONFIDENTIAL ATTORNEYS' EYES ONLY</u>

EXHIBIT C

V. OPINIONS AND THE BASES AND REASONS THEREFOR

A. Overview of the Asserted Patents

Ken Wright and Chet LaGuardia are named as the inventors on the ’164 patent, the ’174 patent, the ’597 patent, the ’157 patent, and the ’422 patent. The ’174 patent, the ’597 patent, the ’157 patent, and the ’422 patent are each a continuation of the ’164 patent. I understand all these patents are owned by DatCard Systems, Inc.

The ’164 patent is directed to a system and method for selecting and automatically recording medical image data onto a data storage medium. *See, e.g.*, ’164 patent col.10 ll.42–67, col.11 ll.23–52.

Around the time of the ’164 patent, the vast majority of hospitals still printed imaging studies to film. Some hospitals had begun to adopt PACS archives. And a few entities had begun documenting and selling systems for burning digital imaging studies to CD.

The ’164 patent provided a new and unique digital storage solution for hospitals and imaging centers. Certain aspects of the “claimed system allow[] for digital medical image data to be produced on a portable digital recording medium such as a CD . . . along with a viewing program, so that a user can use any computer compatible with the CD to view the medical image data on the CD.” *Id.* col.1 l.65–col.2 l.6. Certain aspects also allow “for searching medical data that are related and placing such data on the same CD.” *Id.* col.2 ll.6–9. This solution allowed hospital imaging centers to record selected medical image data on portable digital recording media, along with related medical image data and a viewing program that would allow the recipient to view at least the selected medical image data on any computer – regardless of whether that computer is configured with special software for viewing DICOM images.

The ’164 patent teaches and claims further useful features, such as a plurality of browsing terminals, a feature which enables users to select medical

image data when they are remote from the production station, and printing and affixing a label to the data storage medium using a production station, which allows users to include identifying information associated with the selected medical image data on the data storage medium.

Like the ’164 patent, the ’174 patent is also directed to a method for selecting and automatically recording medical image data onto a data storage medium and a related system. *See, e.g.*, ’174 patent col.9 ll.25–46, col.10 ll.10–34. Furthermore, like the ’164 patent, the ’174 patent involves selecting medical image data, searching for related data based on the user selection, and burning the selected data and the related data to a data storage medium using a production station, along with a viewer for viewing the selected medical image data anywhere.

The ’597 patent is directed to a method and system for automatically generating a portable computer-readable medium containing medical data related to a patient that involves searching for data via two database interfaces. Specifically, the system and method involve searching two databases, via distinct database interfaces, for medical imaging data related to a patient and additional data also related to the patient and generating a portable computer-readable medium, at a production station, containing the medical imaging data formatted in a standard medical imaging format and the additional related medical data.

The ’157 patent is directed to a system and method for generating a portable computer-readable medium containing a patient’s medical data and auditing the medical data produced on the portable computer-readable media.

Finally, the ’422 patent is directed to a system and method for automatically producing medical data on optical storage media after a timeout period expires. The timeout features ensures that all of the patient’s data has arrived before the optical storage media is produced.

B. DatCard's Pacscube Practices the Asserted Patents

I have operated and read the literature regarding DatCard's Pacscube product. Based upon this review, it is my opinion that the Pacscube practices at least one claim of each of the asserted patents. I understand that this opinion is most directly relevant to the issue of patent validity. Accordingly, I expect to set forth the basis of my opinion in more detail in my rebuttal report on the issue of patent validity.

C. Value and Impact of the Patented Products in the Industry

The impact that the Pacscube product has had on medical imaging or radiology departments in hospitals and imaging centers is related to the impact of PACS and the adoption of digital imaging techniques. In the 1970's all medical images were produced on large sheets of film and viewed on a viewbox with a lamp inside, behind the film. They were either acquired primarily on X-ray film, or printed on sheets of film the same size, usually 14 by 17 inches.

During the late 1970's and early 1980's the development of CT scanners first, followed by MRI scanners, led to more images being available in a digital format, while they were often printed on film for viewing by the radiologists. More recently, PACS viewing workstations are used more commonly, and fewer images are printed on film.

When images were usually stored on film, the choice of a method of distribution was easy – by mailing or hand carrying large envelopes full of film, called film jackets. Because the quality of a copy of an original film was not usually equal to the original film, copies of films were used less often. Hospitals bore the large cost of purchasing large amounts of film each year, purchasing the film processors needed to develop the film, maintaining these devices and safely disposing of the chemicals used, and storing the film jackets in a large film file room, really a large warehouse. There were many logistical problems associated with retrieving the film jackets from storage every time

they were needed, keeping track of their current locations, and refiling the film jackets after use. Between ten and twenty percent of the time the film jackets could not be located when they were needed. In addition, the cost of handling medical imaging exams was quite high – about $20 per exam.

DatCard's invention changed all of this. With the introduction of the Pacscube, images and their associated radiological reports could be distributed to patients and physicians on CDs and DVDs. The cost of handling medical imaging exams dropped precipitously to $2 per exam. Misplaced films have become a thing of the past because original films do not need to be checked out to physicians or patients. In addition, patients and physicians can conveniently view images on any personal computer.

Before the introduction of the Pacscube, some images were stored on CDs. However, the systems for doing so were crude and labor intensive. A technician was needed to manually load a CD into a CD burner and to stand by waiting for the burner to store the desired images on the disc. Then, the technician was required to manually write the patient's name and other identifying information on the disc.

Again, the Pacscube changed all this. The Pacscube is an automated, robotic system that eliminates the need for a technician to load and unload discs from a CD burner. In addition, the Pacscube automatically prints a label on each disc, further reducing labor costs and possible errors in the label.

D. BASIC PATENT LAW PRINCIPLES

1. Literal Infringement

I understand that direct infringement of a patent occurs when an entity makes, uses, sells, or offers to sell in the United States, or imports into the United States a product that includes all the limitations of an apparatus claim. To infringe a method claim, an entity must have practiced all steps of the claimed method. However, an entity that is not a direct infringer can still

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DATCARD SYSTEMS, INC., a California corporation, Plaintiff, v. PACSGEAR, INC., a California corporation, Defendant. AND RELATED COUNTERCLAIM	Civil Action No. SACV10-1288 DOC (VBKx) **REBUTTAL EXPERT REPORT OF DR. ALAN ROWBERG, M.D.**

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INFORMATION ON PAGES 66, 77, 78

Exhibit D

As I have previously discussed, Dr. Horii has failed to show that any reference alone or in combination with any other references cited in the Horii report renders the independent claims of the '422 patent obvious. For at least those reasons, the dependent claims also would not have been obvious. In addition, Dr. Horii provides no analysis of the additional elements of the dependent claims. In my opinion, none of the references cited in Dr. Horii's report, alone or in combination, anticipate or render obvious, claims 2, 3, 6, 9, 10, and 13.

VII. OBJECTIVE EVIDENCE OF NON-OBVIOUSNESS

A. Commercial Success and Industry Acceptance

In my opinion, the claimed inventions have achieved commercial success and industry acceptance. Before the introduction of the Pacscube in late 2000, nearly all hospitals and imaging centers provided images to patients and physicians exclusively on film. The very few hospitals and imaging centers using digital media had only the crudest systems in place. CDs had to be manually inserted into a disc drive. Labels were written onto the disc by hand, using a Sharpie pen. The discs contained only images, lacking the critical radiological report. And the disc could be viewed only at specialized DICOM viewing stations.

Today, based entirely on the Pacscube and its imitators, the film-based environment of the past is rapidly disappearing. It is now routine for patients and physicians to receive DICOM medical images on a CD or DVD. The unwieldy practice of carrying films from facility to facility is largely a thing of the past. And, in most cases, the discs are created automatically by a robotic element, labels are automatically and professionally included on each disc, radiological reports are included on the disc, and the disc may be viewed from any computer. Simply put, the Pacscube changed the technological landscape for the distribution and viewing of medical images and reports.

Dr. Horii states that, "in the first two years that DatCard sold its product

plurality of browsing terminals configured to receive a user selection that defines selected medical image data. This is a feature encompassed by at least the '164 and '174 patent claims. DatCard attempted to sell a version of the Pacscube that lacked the ability to search for and record radiological reports to disc and that lacked the ability to interface with a plurality of browsing terminals. The product was unsuccessful and DatCard removed it from the market. This supports a conclusion that the Pacscube's commercial success is attributable to the features of the claims, including the ability to search for data that is related to medical images, such as radiological reports, and support for a plurality of browsing terminals.

As another example, the Pacscube has the ability to record a viewer on a removable medium, as I explained above. This is a feature of at least the '164, '174, and '422 patent claims. A company called Codonics marketed a product that did not include a viewer on the removable medium. I understand that the Codonics product has failed in the market. This also supports a conclusion that the Pacscube's commercial success is attributable to the features of the claims, including the ability to record a viewing on the removable medium.

As yet another example, the Pacscube audits the data that it burns to disc, including a disc-specific identification, an identification of the person who requested the disc, and an identification of the patient whose data is on the disc. This is a feature of at least the '164 and '157 patents. As I stated in my Initial Report, hospitals face serious fines from federal regulators if they improperly release a patient's medical records. The Pacscube's auditing features provide an integrated solution that allows hospitals to track who is requesting patients' data as discs are created. In light of the ease with which the Pacscube allows hospitals to track patients' data, I believe that Pacscube's audit feature is a major factor in the Pacscube's success.

It is unlikely that the Pacscube's commercial success is attributable to

advertising, brand recognition, and similar economic commercial factors. As I mentioned above, when DatCard launched the Pacscube, DatCard was a new company with no brand recognition, whatsoever. At first, DatCard had no marketing staff. Even today, the Pacscube marketing department consists of only three people. Yet, despite DatCard's lack of brand-recognition and very limited marketing resources, and despite the medical profession's caution in adopting new and unproven products, the Pacscube has been a success. In my opinion, this commercial success is evidence of non-obviousness.

B. Satisfaction of a Long-Felt Need

In my opinion, the claimed inventions have satisfied a long-felt, but unsolved, need.

Before the Pacscube, images were usually stored on film, and the choice of a method of distribution was easy: by mailing or hand-carrying large envelopes full of film, called film jackets. As I explained in my initial report, film was expensive to process and store, and there were many logistical problems associated with retrieving the film jackets from storage every time they were needed, keeping track of their current locations, and refilling the film jackets after use. Despite these recognized problems, hospitals stuck with the film-based distribution system.

A few hospitals sought to address the problems associated with film by manually burning studies to CD. As I previously explained, however, these systems were crude and labor intensive. A technician had to manually load a CD into a CD burner and to stand by waiting for the burner to store the desired images on the CD. Then, the technician manually wrote the patient's name and other identifying information on the disc with a Sharpie pen. In my opinion, these manual CD-burning systems did not provide a satisfactory solution to the long-felt problems associated with film-based systems.

The Pacscube changed all of this. The Pacscube is an automated, robotic

system that eliminates the need for a technician to load and unload discs from a CD burner. In addition, the Pacscube automatically prints a label on each disc, further reducing labor costs and possible errors in the label. With the introduction of the Pacscube, images and their associated radiological reports could be distributed to patients and physicians on CDs and DVDs. The cost of handling medical imaging exams dropped precipitously to $2 per exam. Misplaced films have become a thing of the past because original films do not need to be checked out to physicians or patients. In addition, patients and physicians can conveniently view images on any personal computer.

As discussed above, the Pacscube's commercial success is evidence that the Pacscube did, in fact, provide a superior solution to manual CD systems and satisfied the long-felt problems associated with film-based systems. Dr. Ratib – the developer of the manual CD system described in the Ratib article – bought several Pacscube systems for UCLA after he published the article. In my opinion, this is evidence that Dr. Ratib's manual CD system failed to adequately satisfy the needs of UCLA and is evidence of non-obviousness.

C. <u>Copying</u>

In my opinion, there is evidence that Pacsgear replicated the Pacscube, which had been widely adopted prior to Pacsgear's entry into the market. Pacsgear had access to the Pacscube (*see, e.g.*, Internal Pacsgear email from Thomas Pickard to Chris Barnett and Abdul Khatri at PG010921, showing access to Pacscube brochure) and introduced a product with features that are substantially similar to the Pacscube's features. For example, Pacsgear's product included a robotic production station, just like the Pacscube did. (*See also* Email from Brian Cavanaugh at Pacsgear to Skip L. Kennedy at Kaiser Permanente at PG010643, "The plan is to demonstrate CD burning to a single (non-robot) CD writer at RSNA. It will be released early in 2007, followed by a robot-type system for not only patient CD's, but also for backup.")

In my opinion, the fact that Pacsgear's engineers abandoned the single (non-robot) CD writer found in the prior art in favor of the unique robotic production station design found in the Pacscube is strong evidence of copying and non-obviousness.

I understand that DatCard has previously sued Codonics, Inc. for patent infringement. I also understand that the accused Codonics products incorporated the Pacscube's patented features, including the robotic production station design. Also, in my initial report, I identified a number of other companies that infringe DatCard's products. These companies are also using the unique patented features of the Pacscube, including the robotic production station design. This, again, is strong evidence of copying and non-obviousness.

D. Settlement

I understand that a competitor's settlement with a patent owner can evidence the competitor's respect for the patented invention. I also understand that Codonics – a direct competitor of DatCard – reached a settlement with DatCard after DatCard sued Codonics for infringing the '164 patent. As part of that settlement, Codonics exited the market. In my opinion, Codonics' willingness to reach a settlement so averse to its own commercial interests evidences Codonics' respect for the patented invention. This is strong evidence of non-obviousness.

VIII. DATCARD'S PACSCUBE PRODUCT PRACTICES THE ASSERTED PATENTS

As I stated in my Initial Report, I have operated and read the literature regarding DatCard's Pacscube product. Based upon this review, it is my opinion that the Pacscube practices at least one claim of each of the Asserted Patents. My opinion is explained in greater detail below.

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

\- - -

DATCARD SYSTEMS, INC., a California corporation, Plaintiff, vs. PACSGEAR, INC., a California corporation, Defendant.	Case No. SACV 10-1288 DOC (VBKx)

(Complete caption on next page.)

NON-CONFIDENTIAL PORTION

30(b)(6) DEPOSITION OF DATCARD SYSTEMS, INC.

BY AND THROUGH KENNETH LOUIS WRIGHT

LOS ANGELES, CALIFORNIA

THURSDAY, AUGUST 4, 2011

ATKINSON-BAKER, INC.
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REPORTED BY: MARY FERGUSON, CSR NO. 8769

FILE NO.: A5073A3

Exhibit I

involved in the implementation or the installation of it, but I was involved in committees that would review feature sets and function sets within the electronic medical record.

Q. That's different than the PACS, which is --

A. Very much so.

Q. This is a -- instead of having a paper file on a patient, you would have some sort of storage device that would have all the patient's information?

A. Yeah, like a PACS, but not containing medical images.

The patient's chart, if you will, would be stored electronically and viewed throughout the hospital on workstations, I guess is the best way to describe it.

Q. So more or less, a shift from traditional paper files with all the reports, putting their digitizing, all that, and having it stored on a computer and accessible through your computer needs?

A. That's correct.

Q. Any other projects that we haven't discussed?

A. There probably are, but I can't remember, to be very honest with you.

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Q. And at some point, you mentioned your title changed to project analyst, dealing with medical infomatics.

Why the title change?

A. I think it was an administrative decision in the fact that when they looked at the size of the physical network we were building, the switches, the routers, how much money that was costing the hospital, mixed with how all these systems become integrated at some point, the HL-7, they decided to move me from the radiology department, who had control of my position, into the IS department, and they moved quite a few of us.

They took the individual that was in the laboratory, the individual that was in the nursing, and they created a medical infomatics department. They moved us all into there -- into one room, if you will, so that we could begin to collaborate and share knowledge.

Q. So, essentially, it was just kind of in furtherance of your role as PACS administrator, just a title change and logistical changes to facilitate that?

A. To some extent, but with that change comes my interaction in many other projects that I would

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have probably never been involved in, unless the group was put together as a whole.

So I participated in a lot, such as the electronic medical record project and things of that nature.

As a PACS administrator, I would not have had the opportunity to participate in such a thing.

Q. When did you, in this time frame, work on the various projects?

For example, when did you work on the HL-7 projects?

A. Probably throughout my IS career at Hoag. From the time I was a radiology systems administrator through the end of my career. There were many, many interfaces that came about, and we would work on it from time to time.

Q. So from approximately 1990 to 1999, you were involved in HL-7 projects?

A. Correct.

Q. Do you know when the HL-7 standard came into being?

A. I do not.

Q. I guess during that time period before things went digital, how were -- if one wanted to -- let me rephrase the question. Starting over.

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If one wanted -- if a doctor wanted to send a patient and their records to another doctor for consultation, what would be sent?

A. It would depend on what he needed sent, I guess is the question. If it was medical record information, it would be sent in a way I probably couldn't answer. I don't know that side of the world.

Q. Let's just -- for example, radiology. Say wanted a second opinion on an X-ray.

What would be sent from one doctor to the other doctor in terms of -- for that review process?

A. It would be -- the hospital would send the physician a copy of the X-rays, utilizing film, and a printed copy of the diagnostic result that would accompany that.

Q. So that's pre-PACS, during the 1990 to 1999 time period?

A. That's correct.

Q. What is the -- the diagnostic results, is that the text report?

A. That is the result that's related to the images.

So the images are taken, they're interpreted by a radiologist, and then a diagnostic

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would all work. 10:39:28
Q. There would be some interconnectivity between the various reports relating to that individual patient? 10:39:32
A. One more time, if you could repeat that. I am sorry. 10:39:40
Q. Sounds like there would be some interconnectivity association within the PACS or computer systems to connect the diagnostic report with the associated X-ray, for example. 10:39:49
A. There's a direct correlation with a diagnostic report and a specific examination, yes. 10:40:00
Q. With these images, did the -- once they are digitized and they wanted to have a second opinion, for example, how were they transferred from one medical facility to another in the digital scheme? 10:40:06
A. In 1999, that era, they weren't. 10:40:56
Q. Okay. 10:41:01
So in 1999 images -- you were still putting the X-ray in the envelope with a diagnostic report, and either sending it directly to the other medical facility or having the patient act as the courier? 10:41:03
A. That is correct. 10:41:19
Q. And at some point -- go with CDs, as the mode of transportation to facilitate the transfer of 10:41:34

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these types of images, came into being; is that true? 10:41:52
A. That's true. 10:42:00
Q. When did that happen? 10:42:00
A. After we invented the product. 10:42:01
Q. By "the product," you mean PacsCube? 10:42:03
A. PacsCube, that's correct. 10:42:07
Q. Prior to 1999, were you aware of any systems that -- strike that. 10:42:17
Prior to the end of 1999, were you aware of any situations where medical images were stored on CDs? 10:42:28
A. I knew of a couple of systems that could actually record a medical image to a CD, one being the eFilm workstation, and I don't recall knowing any others at that time. 10:42:40
Q. What is the eFilm workstation? 10:42:56
A. It is an independent DICOM-compliant workstation that receives and displays images. You can load that software on any Windows-based PC. 10:43:07
Q. So instead of being affiliated with one of the major manufacturers, it was its own -- it had its own software for viewing images at a workstation? 10:43:23
A. That is correct. 10:43:37

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Q. Did it -- okay. 10:43:38
You said that this eFilm workstation allowed for burning images onto a CD? 10:43:56
A. Yes, it did. 10:44:01
Q. When did you learn of that? 10:44:02
A. Probably in 1999 at some point, I am guessing. 10:44:04
Q. Where were you when you became aware of that; how did you become aware of that? 10:44:15
A. I don't recall, to be honest with you. 10:44:19
Q. Was it at a trade show, Google -- 10:44:23
A. No, I may have seen it on a website. I don't recall how I found out about it. 10:44:26
Q. Did eFilm actually sell a workstation with all the software loaded on it, or did it just sell the software and gave instructions on how one would load it on to their own workstation? 10:44:37
A. Neither. It was free. 10:44:51
Q. It was free, okay. 10:44:54
It was software, then? 10:44:56
A. Yes. 10:44:57
Q. They didn't give workstations away for free? 10:44:57
A. Right. 10:45:00
Q. I missed that one, if they did. 10:45:02

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Was it essentially viewing software; is that what we are talking about? 10:45:04
A. That is correct. 10:45:09
Q. So you could use this eFilm software to view electronic medical images; is that correct? 10:45:14
A. That's correct. 10:45:24
Q. And you could also use this eFilm software to burn medical images on CDs? 10:45:25
A. That is correct. 10:45:32
Q. And other than the utilization of the eFilm software to burn medical images onto CDs, were you aware of any other instances where medical images were burned onto CDs? 10:45:40
A. I believe TDK had a product. 10:46:05
Q. What did their product do? 10:46:11
A. I am not a hundred percent certain what it did, but I do know that it could burn medical images onto a CD. 10:46:13
Q. When did this TDK -- I guess -- was it TDK software or a combination of software and a workstation, CD-burning robot? 10:46:34
A. I don't know; I am sorry. 10:46:49
Q. When did you learn of the TDK device? 10:46:51
A. Sometime late '99, I want to say. 10:46:54
Q. The eFilm software, how did that work? 10:47:11

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A. Once you loaded it onto a PC, installed it, you then had to configure the DICOM aspects of it to receive images, and when it received images, it would put them in a list for you to type in the patient's name, select the patient, select the image, and the images would display.

Q. So the workstation that the eFilm was stored on had its own type of mini PACS; is that a fair summation?

A. It had its own image server and its own database.

I am not sure I would call it a mini PACS, because it lacked a lot of features of a PACS, but it definitely was a mini storage device that could display its own images.

Q. What additional features would a PACS have that this eFilm workstation didn't have?

A. Global work list, the ability to display results, the ability to archive large amounts of data for years upon years upon years.

Q. Size of the hard drive?

A. Technologically, it goes well beyond that, but I suppose you could sum it up to be the size of the hard drive.

Q. When you say the global work list, that

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means that -- you are referring to what we were talking about with G.E., where at a single workstation, you could -- at any workstation, you could access the PACS database?

A. Yes.

Q. And with the eFilm workstation, it was self-contained?

A. That is correct.

Q. Would there have been a way to hook up a computer next to it and have that computer search the eFilm database?

A. Not that I know of.

Q. Would it have been somewhat easy to do, to have an eFilm workstation into a network of some sort, which would allow for the access of the eFilm's database?

A. To possibly access its database, but not for viewing images.

Q. Why wouldn't it be able to view images?

A. It didn't have a mechanism built to move the images between systems.

Q. But if I was just creating a network that allowed for the images to be transferred, would that -- there would be no way to create a workstation next to it, the eFilm workstation, have

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it networked in, so it could access the database of the eFilm workstation?

A. You could transfer them between the two utilizing the DICOM standard, but that would -- if -- if a CT scan was contained on one and you wanted to view it on the other, you would have to physically go to the CT workstation, send it to the other one, and then sit down and view it at the other one. It doesn't make for a very good workflow environment.

Q. Why wouldn't you be able to just access the eFilm workstation and have it --

A. Its architectural design didn't allow that. They were self-contained workstations.

Q. Oh, the workstation, okay.

But there are workstations which could be configured to allow such a transfer?

A. PACS workstations, yes.

Q. Did you get a demonstration of an eFilm workstation sometime in the 1999 time period?

A. 1999, no.

Q. That's when you became aware of it.

When did you get -- I guess you became aware of it in 1999, but you didn't get the demonstration until sometime later?

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A. Well, it was free, so they really didn't have any incentive to demonstrate it to you.

Q. Exactly. Why pay somebody to demonstrate it. Fair enough.

So you acquired the software for free sometime in 1999 and began using it yourself?

A. Yes, that is correct.

Q. And you downloaded medical images onto a workstation that also had this eFilm software?

A. Yes.

Q. And did it function similar to the way we previously discussed, where you would type in a patient's name, and it would search the database on the eFilm workstation for medical images relating to that patient?

A. That is correct.

Q. And then, if you wanted to burn a selected image onto a CD, the eFilm software allowed for that?

A. You could burn a selected image onto a CD, yes.

Q. Did eFilm have just one piece of software or did it have multiple pieces of software?

A. It just had one piece of software.

Q. I saw somewhere, there's a reference to

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eFilm and eFilm Lite. 10:53:22
Is there any difference between those two pieces of software? 10:53:24
A. It's in the same suite, so if you asked me about eFilm workstation, eFilm workstation includes eFilm Lite, or it did in 1999. 10:53:28
Q. What is the difference between eFilm and eFilm Lite? 10:53:40
A. EFilm Lite is the viewing software that lives on the CD when you burn a CD. 10:53:44
Q. Why would you want eFilm Lite to be on a CD that you burn with a medical image? 10:54:01
A. So you can display the images that are on the CD. 10:54:10
Q. And you can do that on any PC or Mac? 10:54:13
A. Windows-based PC. 10:54:17
Q. You don't like Macs? 10:54:19
Okay, so essentially, you could use the eFilm software to burn an image on a CD. 10:54:30
Along with the image would be this eFilm Lite, and then you could take that to any -- your home PC or anywhere and view the image at that PC; is that a fair summary? 10:54:42
A. That's a fair summary. 10:54:52
Q. Where were you in 1999 when you burned this 10:54:54

CD using the eFilm software? 10:55:26
Were you at work; were you at home or -- 10:55:29
A. I don't recall. 10:55:32
Q. One or the other? 10:55:32
A. I really don't recall, to be honest with you. 10:55:35
Q. Did you download it over the internet, the software; is that how they -- 10:55:38
A. I believe I did, yes. 10:55:43
Q. You used the word "suite" earlier, eFilm suite. 10:55:54
What did you mean by that? 10:55:59
A. Well, it had eFilm, the viewing workstation, and then eFilm Lite mixed with a small imaging server that allowed it to receive images. 10:56:00
Q. So there's -- the eFilm software that was on the workstation, what was the difference between that and eFilm Lite, if any? 10:56:18
A. There were a few less viewing features. What those were, I can't remember, but there was a small difference, and it would only have access to the images that were on the disk, itself. 10:56:42
Q. The eFilm Lite would only have access to the images on the disk, itself -- 10:56:56
A. That's correct. 10:57:04

Q. We were doing a great job of not talking over each other, but I notice we did. 10:57:04
A. Sorry. 10:57:09
Q. Actually, my fault, as well. 10:57:10
Did you know any -- of any medical facilities which were using the eFilm software in the 1999 time period? 10:57:19
A. The University of Toronto. That's the only one I know. 10:57:29
Q. How do you know it was used at the University of Toronto? 10:57:37
A. That's where it was created. 10:57:45
Q. Do you know who created it? 10:57:46
A. Greg Couch, I believe. 10:57:48
Q. Do you know when eFilm was created, the software was created? 10:58:07
A. I do not. 10:58:11
MR. HOLBROW: We've been going for a little bit. 10:58:21
You want to take a quick break? 10:58:23
THE WITNESS: Sure. 10:58:25
THE VIDEOGRAPHER: We are going off the record at 10:58. 10:58:27
(Recess taken.) 10:58:31
THE VIDEOGRAPHER: We are back on the record at 11:06. 11:06:13
BY MR. HOLBROW: 11:06:19
Q. You realize you are still under oath? 11:06:20
A. Yes. 11:06:22
Q. Earlier we were talking about the DICOM standard; do you recall that? 11:06:23
A. Yes. 11:06:28
Q. What is your understanding of the DICOM standard and how it -- let me back up, be a little more specific. 11:06:28
What is your understanding of the DICOM query retrieval standard? 11:06:36
A. Today or in 1999? 11:06:41
Q. In 1999. 11:06:44
A. In 1999, not much, other than I knew that it was a standard for the searching and retrieval of images. 11:06:45
Q. Between 1999 and now, do you have a fuller understanding of the DICOM query retrieve function? 11:06:56
A. Yes, I do. 11:07:20
Q. What is it? 11:07:20
A. It's just as I described in my prior testimony, although I understand it at a much deeper level. I actually write code and things of that nature, interacting with it. 11:07:21

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KENNETH LOUIS WRIGHT AUGUST 4, 2011

my own technology obstacles, because I needed to learn some new languages and learn how to do things differently. 11:46:43 11:46:47 11:46:50

The -- we needed a DICOM server or an image server to receive images, and I needed a robotic to be able to produce those images automatically to CD for us. 11:46:54 11:46:59 11:47:03 11:47:07

Q. When you refer to the DICOM server, you are talking about a computer, or what are you referring to? 11:47:08 11:47:11 11:47:16

A. Piece of software; an image server, DICOM server is something that's receives medical images, utilizing the DICOM standard. 11:47:16 11:47:21 11:47:24

Q. Did you use the eFilm server? 11:47:31

A. Early on, yeah, I did. We made an agreement with eFilm to utilize that. 11:47:36 11:47:39

Q. Their software? 11:47:42

A. That's correct. 11:47:43

Q. What other obstacles did you encounter? 11:47:46

A. That was about it. 11:47:51

Q. So the first obstacle was satisfied by the Rimage CD production unit, and the second obstacle was satisfied by the eFilm server; is that a fair summary? 11:47:53 11:47:58 11:48:01 11:48:05

A. That is correct, yes. 11:48:06

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Q. Five minutes on the DVD. 11:48:07

What -- just if you can take me through chronologically what steps you took after this meeting with Mr. LaGuardia to -- that relate to your conception of the product. 11:48:11 11:48:25 11:48:28 11:48:33

A. Could you ask the question one more time? 11:48:41

Because I lost track in the steps that I took chronologically from when to when? 11:48:44 11:48:46

Q. Following your discussion with Mr. LaGuardia, I guess to the point you had what you consider to be your final conception of the device. 11:48:50 11:48:51 11:48:58

A. Well, from the time that Chet and I discussed it, I went through a lot of program iterations of it, doing trial and error and testing on my own, in my own time. 11:49:10 11:49:13 11:49:16 11:49:21

And, you know, I ran quite a few things past Chet, as far as some of the feature and functions, and he would give input here or there based on what he thought feature and functions that I should put into it. 11:49:24 11:49:28 11:49:30 11:49:34 11:49:36

Once he found the Rimage unit, I then had to deal with the Rimage API. 11:49:37 11:49:41

Q. The Rimage what? 11:49:44

A. API, the application program interface, to be able to understand how to make my software that I 11:49:45 11:49:48

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wrote interact with the Rimage API, so we could utilize the robotic. 11:49:52 11:49:55

Q. And what features did you discuss with Mr. LaGuardia in terms of whether to include or not include? 11:49:58 11:50:03 11:50:06

A. Things to be able to include reports or to be able to de-identify patients. Whether to make this a web-based application where anybody could do it across the internet, things -- these were all ideas that I had, and I respect Chet a lot in knowing workflow and healthcare, so I would bounce a lot of these ideas off Chet. 11:50:07 11:50:15 11:50:24 11:50:27 11:50:30 11:50:33 11:50:37

MR. HOLBROW: You want to switch out the DVD? 11:50:40 11:50:42

Off the record. 11:50:43

THE VIDEOGRAPHER: This completes DVD 1, Volume I, in the continuing testimony of Kenneth Wright. We are going off the record at 11:50. 11:50:43 11:50:46 11:50:58

(Recess taken.) 11:51:01

THE VIDEOGRAPHER: This is the beginning of DVD 2, Volume I, in the continuing testimony of Kenneth Wright. 11:55:38 11:55:39 11:55:43

We are back on record at 11:55. 11:55:44

BY MR. HOLBROW: 11:55:48

Q. Do you understand you are still under oath? 11:55:48

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A. Yes, I do. 11:55:54

Q. Before we took the break, we were talking about kind of the conception process, and you mentioned you had discussions -- ongoing discussions with Mr. LaGuardia regarding developing the product that was ultimately patented. 11:55:55 11:55:58 11:56:03 11:56:06 11:56:12

For how long a period of time did you have these questions or discussions with Mr. LaGuardia regarding what to include or not to include in the product? 11:56:14 11:56:22 11:56:24 11:56:29

A. I am guessing quite a few months, probably. I don't really recall, to be honest with you. 11:56:31 11:56:35

Q. Was there a date at some point a few months later, November, December time period, where you said, "Okay, now I have got it; this is what we are going to do," or did it continue to develop after that? 11:56:50 11:56:59 11:57:01 11:57:04 11:57:07

A. Well, it's always continued to develop, so I really can't tell you at what point in time I said, "Okay, I have everything I need," so to speak. 11:57:07 11:57:11 11:57:15

I know that I had working pieces of software by probably the first part of 2000, but what particular month, I don't know. 11:57:22 11:57:33 11:57:35

Q. What did this software do? 11:57:37

A. It would receive studies and make CDs 11:57:40

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mechanism. Matt at that point had no exposure to DICOM, so part of the process was me teaching Matt DICOM as we went and him helping us come up with solutions to that. 15:26:14 15:26:18 15:26:21 15:26:25

Q. When did you decide that that was a problem that needed to be resolved? 15:26:40 15:26:44

A. I don't recall. 15:26:46

Q. How long after you determined that it was a problem did you come up with the solutions? 15:27:00 15:27:02

A. Well, I came up with the solution fairly quickly, but I certainly didn't have the skill set to write it, myself. 15:27:05 15:27:12 15:27:16

So after hiring Matt, Matt certainly had the skill set to do it so -- I knew it was an issue pretty clearly, pretty quickly. 15:27:17 15:27:20 15:27:26

Q. So the programming took a little bit of time, but the solution to the obstacle you came up with on your own pretty quickly? 15:27:28 15:27:36 15:27:39

A. Yeah. Well, I knew there was going to be a problem before I ever started programming. Just how big is the problem? You learn a lot as you go, so. 15:27:42 15:27:45 15:27:47

Q. Okay. 15:27:51

The program took a little more time, but the solution that you came up with, you came up with pretty quickly? 15:28:01 15:28:03 15:28:05

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A. Yes. 15:28:06

Q. Turning back to Claim 9, do you have it in front of you? 15:28:08 15:28:41

A. Yes. 15:28:41

Q. It talks about the selected medical image data. 15:28:41 15:28:55

Where is that found, based on Claim 9? 15:28:55

A. I am not certain I understand the question. 15:29:04

Q. Okay. 15:29:06

It talks about selected medical image data. I am not sure what database it is going to or what -- from that claim language, where it is going to find the selected medical image data. 15:29:07 15:29:11 15:29:14 15:29:17

A. I am still not clear on what you are asking. 15:29:22 15:29:25

Yeah, I am -- can you phrase it differently, maybe? Sorry. 15:29:32 15:29:35

Q. I will try to explain. 15:29:36

We got the people at the browsing terminals selecting images. 15:29:37 15:29:41

Where are they looking to find those images? 15:29:43 15:29:45

A. They are looking at the PACS. 15:29:46

Q. Is that stated anywhere in Claim 9 that you can see? 15:29:57 15:30:01

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MR. STEWART: I am going to renew my objection from before. He is not a patent attorney, but he can answer as best he can. 15:30:04 15:30:06 15:30:09

THE WITNESS: I do not know. I am sorry; I don't know. 15:30:43 15:30:43

BY MR. HOLBROW: 15:30:49

Q. Does the eFilm allow to read text reports or just images? 15:30:49 15:31:14

A. Just images, I believe. 15:31:15

MR. HOLBROW: I will get this marked as Exhibit 4, patent number 7,729,597. 15:33:19 15:33:21

(Defendant's Exhibit 4 was marked for identification.) 15:33:21 15:33:27

BY MR. HOLBROW: 15:34:12

Q. If you can turn to the claims. 15:34:13

If you look at Claim 1, the term "automatically" is used pretty liberally. 15:34:38 15:34:45

If you could take a look at that language. 15:34:49

Focusing on "automatically," is "automatically" intended to mean it requires no human interaction? 15:35:31 15:35:35 15:35:38

MR. STEWART: Again, I will renew my objection that he is not a patent attorney, but he can answer to the best of his ability. 15:35:43 15:35:45 15:35:47

THE WITNESS: I can't really speculate on 15:35:54

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what he meant when he wrote "automatically" as many times as he wrote it here in this claim. 15:35:55 15:35:59

BY MR. HOLBROW: 15:36:01

Q. In reading that claim, what is your interpretation of "automatically"? 15:36:01 15:36:04

A. Well, in my interpretation of "automatically" within this claim is when a user makes some sort of action that denotes a response, the computer is going to automatically get them that response. 15:36:06 15:36:08 15:36:15 15:36:20 15:36:25

Whereas if a user provokes an action, such as a job request, the system will then automatically retrieve, collect and produce the job without further human intervention. 15:36:25 15:36:30 15:36:34 15:36:37

So the underlying computer operations are what I would deem happen automatically. 15:36:38 15:36:43

Q. In Claim 1, is it your understanding that a person would request medical data related to a patient, and as a result of that, without any further human intervention, the steps that follow occur? 15:37:20 15:37:24 15:37:34 15:37:38 15:37:47

A. When you say "steps as follows," as the steps written in this claim, or are you saying the steps that follow in a generic sense? 15:37:50 15:37:54 15:37:55

Q. No, the steps that follow in this claim. I 15:37:57

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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

DATCARD SYSTEMS, INC., a California corporation, Plaintiff, vs. PACSGEAR, INC., a California corporation, Defendant.	Case No. SACV 10-1288 DOC (VBKx) (PER PROTECTIVE ORDER SECTION 11 THIS TRANSCRIPT HAS A TEMPORARY "CONFIDENTIAL - OUTSIDE COUNSEL ONLY" DESIGNATION FOR A PERIOD OF 14 DAYS AFTER THE DEPOSITION IS RECEIVED.)
COMPLETE CAPTION ON NEXT PAGE.	

DEPOSITION OF

ALAN H. ROWBERG, M.D.

LOS ANGELES, CALIFORNIA

DECEMBER 16, 2011

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Exhibit J

CONFIDENTIAL
ALAN H. ROWBERG, M.D. A50BB63 DECEMBER 16, 2011

Q. And is the portion that he highlighted and underlined on that page the same sentence that you came up with? 10:32:04 10:32:05 10:32:10
A. It is. 10:32:12
MR. HOLBROW: Why don't we take a break. 10:32:13
VIDEOGRAPHER: Watch your microphones when you get up. Now going off the record. The time is 10:32 a.m. 10:32:15 10:32:18 10:32:21
(Recess from 10:32 a.m. to 10:40 a.m., after which Mr. Martin is not present in the deposition room.)
VIDEOGRAPHER: Now back on the record. The time is now 10:40 a.m. 10:40:06 10:40:07
Counsel? 10:40:10
BY MR. HOLBROW: 10:40:11
Q. You're all set? 10:40:11
Okay, when we broke you were referring to a sentence in column 2 that referred to "medical exam data." Do you recall that? 10:40:13 10:40:16 10:40:20
A. Yes. 10:40:23
Q. And is there anything in the patent that teaches that the medical exam data includes HL7 reports or Mitra broker reports? 10:40:26 10:40:32 10:40:35
A. I don't recall either the phrase "HL7" or "Mitra" -- 10:40:43 10:40:46

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Q. Okay. 10:40:49
A. -- in the patent specification. It could well be there. 10:40:49 10:40:59
Q. And you agree that the HL7 reports and the Mitra broker reports are text reports? 10:41:04 10:41:09
A. Yes. 10:41:11
Q. Not medical images. 10:41:11
A. Correct. 10:41:12
Q. And do you recall -- you've gone through it several times now already. Is it fair to say that there's nothing in the specification that refers to HL7 reports, Mitra reports, or any type of text report? 10:41:20 10:41:25 10:41:27 10:41:29 10:41:34
A. I didn't see that phrase as I was skimming through. 10:41:37 10:41:39
Q. I'm not talking about a specific phrase. I'm talking about the general topics of HL7 reports, Mitra reports, or any text reports. 10:41:40 10:41:42 10:41:46
A. Only that one sentence that I found. That's the only sentence I found that relates to that. 10:41:48 10:41:50 10:41:53
Q. And that's the column 2, line 6? 10:41:53
A. Correct. 10:41:58
Q. Okay. And is there anything in the patent, other than the use of the term "medical exam 10:41:59 10:42:07

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data," that suggests that that term means text reports or HL7 reports or any Mitra reports? 10:42:11 10:42:16
A. I haven't seen anything else, no. 10:42:27
Q. And if you turn to Figure 5 of the '164 patent, and in box 178 it says "select exams"? 10:42:31 10:42:44
A. Yes. 10:43:02
Q. Do you see that? Is that referring to the exam data that you mentioned in column 2? 10:43:02 10:43:06
A. In our PACS system I'm used to thinking of exams as including reports. Here the following block says: 10:43:32 10:43:37 10:43:42
Find related image data.
And so I believe here these two blocks are related to images rather than to nonimage data described in column 2. So I think this "selected exams" refers to the images for that patient. 10:43:47 10:43:50 10:43:58 10:44:04
Q. Is there any other place in the patent that talks about -- that further defines what the exam data is, besides Figure 5? 10:44:08 10:44:12 10:44:17
A. The word "exam" is not used frequently in this specification. The phrase "image data" is usually used instead of exam, and so I guess the place I'd expect to see it is where there's a 178 item in the long section on the following page. 10:44:28 10:44:32 10:44:45 10:44:52 10:44:58
Q. Maybe column 8, line 38. It looks like 10:45:16

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178 is highlighted. 10:45:24
A. So in 178 they're selecting exams, and I would take that to mean the images. And then the following three lines: 10:45:38 10:45:41 10:45:45
The user is then asked in step 180 if he or she desires to find related data of that patient for comparative study.
Their "related data" does not have the word "images." That might mean HL7 reports. It also might mean comparative exams and be referring to image data. 10:45:52 10:45:55 10:46:00 10:46:08
Q. Okay. So you're saying that the next -- that last sentence where it says: 10:46:10 10:46:13
The user is then asked in step 180 if he/she desires to find related data of that patient for comparative study.
The use of "related data" there could mean reports? 10:46:23 10:46:27
A. Because it doesn't say "image," it's at best vague. 10:46:28 10:46:34
Further down there's "related data storage," field 254. That goes back to a different figure, I think. 10:46:40 10:46:44 10:46:48
(Reviews document.) 10:46:59

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15 (Pages 54 to 57)

cookbooks and rule books, but hard to do between October and March for most companies.
Q. Right.
A. By the next year, and you haven't asked that yet --
Q. Let me just finish up on this. And how many of these disk '95 CDs did your group make?
A. Well, the ad hoc group was the sponsoring group. My group at Duke actually collected the image data in proprietary formats and put it into a generic raw format, digital format, so that the group at Brown could enter it into DICOM. So there was parallel efforts. We didn't -- this disk, we didn't -- the disks, we didn't make. So it was a team effort where we collected image data in all the different flavors that the big vendors produced.
Q. And what type of flavors are you talking about?
A. Boy, oh, boy that was a long time ago.
Q. Just some examples?
A. Just they all would have their proprietary headers, and we had our own inhouse programmers that could strip away headers and convert it to our data. They were cooperative, you know, a lot of times back then the problem was proprietary, by definition was proprietary. There was reasons for them to not share

Page 22

information. With us, an academic center, they would say okay, here's an angiogram, this is the way we build it, and my lab did that, you know, we said okay, we aren't telling anybody. So we took the information they gave us, we converted it to just block pixel data and just a number of rows, a number of columns, which would not even be where they stored things internally. And then we passed it along to the folks at Brown, who then attached the DICOM wrapper around it. And then I'm trying to remember who actually made, and I think the group at Brown made the master CDs. And the reason for the master CDs, they made the final master CD, but again we were trying to give the participating companies as much lead time. So we tried to get one off copies to the participating companies around Christmastime for a March demo. And with the idea that for the March demo, sometime in the February, March time frame, everything was locked down, I want to say we pressed about 5,000 or so, just to hand out to participants at the meeting.
Q. Okay. And then those individuals, whoever had it, could display those images on their proprietary work stations?
A. In 1995 the idea was to go, we encouraged people to go from booth to booth and say do you support the DICOM standard, show me. That was the idea.

Page 23

Q. Okay.
A. You know, and they said sure we do, whether or not they had product was a different question. We could then say okay, here it is, and the idea this was relatively novel in 1995, that they could take a pseudo patient and show that you could play that at -- I want to say there was maybe not 20 vendors, but around that many in 1995 that you could go to.
Q. Okay. So that was kind of the beginning of uniformity connection with reviewing image, medical imaging?
A. Right. We proved that if you followed the cookbook, you know, it was a bit of a, a little bit of a logical stretch. We took patient data, actually probably about 15 to 20 different patients. We made a pseudo patient with the table of contents index, who this is, who their doctor is, what they are there for, and then people could view them on the different vendor work stations and prove the concept.
Q. And that was in 1995?
A. (Whereupon, witness nods head.)
Q. Did the American College of Cardiology -- was that the group you were working in connection with?
A. I was a consultant to the American College of Cardiology, yes.

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Q. Okay. And did they produce any additional disks for subsequent shows?
A. Yes, they did, actually more than one probably.
Q. Okay. Did they do one for 1996?
A. They did.
Q. And did it essentially contain the same types of images?
A. The changes that were made for 1996, again, you're jogging my memory, were twofold. One, we wanted to include other cardiac image data other than just angiograms so we used nuclear medicine. Again, we made one pseudo patient that now came with x-ray angiograms of their heart. They had echocardiograms, had ultrasound, and they had nuclear medicine images of the heart, too. They were not all the same patient really. And even though the demo in '95 proved its point to the attendees, it was basically at the time a nice, you know, a nice cupholder, and because there's no way to play it for them. So we decided for the '96 demo to include a viewer, a program on it, that they could pop it into any Windows PC and start the viewer and see for themselves the images. So now they could go one step further, not just see that you could exchange -- in 1995 going booth to booth was supposed to simulate hospital to hospital. But, you know, physicians are hard to

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please and that satisfaction lasted only so long. Now to be able to bring it up on their own PC to show that, wow, the standard is universal enough that you can do this on what was relatively inexpensive technology in 1996.

Q. And do you know the type of viewing software that was installed on the '96 disk?

A. The 1996 disk, to my memory, now they sort of became again, the demo was managed by the same group, the successful work group, and we farmed out the different parts of the construction because they are always strapped for time. The Brown group was not involved in 1996. The Duke group still was, and I believe that we contracted with research programers at Cleveland Clinic cardiology, Dr. Jim Thomas's laboratory, one of their programers. They were awarded a modest fee to develop a Windows PC program that would start up this CD and play it.

Q. Okay. So the '96 disk anyone could just take home, put in their own home computer, and open up all the medical images, and view them with this viewing software, is that accurate?

A. Right, and complain about the speed, because this is a lot of data and these were dynamic images, but at least they would go step, step, step.

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Q. Okay.

A. This was a building education, but by that time the difference was that by the '96 demo now all the vendors were showing their own products that were actually doing all of this.

Q. Viewing stations and --

A. Viewing stations, right.

(Whereupon, Deposition Exhibit 77 was marked for identification.)

Q. This is an article entitled "Evolution of the Filmless Cardiac Angiography Suite: Promise and Perils of the Evolving Digital Era," Bates stamped PG15924 through 15927. Have you seen this article before?

A. Yes.

Q. Okay. I'd like to turn your attention to page 43 of the article, and the second column, there's a paragraph that begins at the 1996 ACC scientific sessions?

A. Uh-huh. Yes.

Q. Were you in attendance at that?

A. Yes.

Q. Where was that?

A. In '96 was I believe Orlando.

Q. And is this the show that you were talking about where the '96 disk was provided?

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A. The second one.

Q. What do you mean, the second one?

A. This is the first one (indicating), and then you asked if another one was done.

Q. Okay. So the '96 show that we were talking about with the '96 disk was presented at this 1996 ACC scientific session?

A. Yes.

Q. And are you familiar with Dr. Nissen?

A. Yes.

Q. Okay. And who is Dr. Nissen?

A. Well, Dr. Nissen now is very, very famous. Where did I just see him? Consumer Reports this month. But at the time he was the co-chair, and in his role in the American College of Cardiology, he was the co-chair of the ad hoc group of the three organizations I referred to earlier. At the time he was at the Cleveland Clinic, interventional cardiology. And he was really one of the big pushers within the clinical society to move this whole issue forward.

Q. Okay. And so I guess just reading this paragraph, that's consistent, this confirmation, with your recollection that the CD-ROM was provided with a viewer on it?

A. Yes. It mentions educational materials, and

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whereas in the '95 demo we also put together kind of a nice little book to explain it all to people, and we thought it would be really neat because people were going to be very quickly disappointed by how slowly the images viewed on their PC at home. And we put in a format that they could view at home. We tried to educate them on this.

Q. So there was a textual component to the '96 disk?

A. Yes. Actually it was the World Wide Web where we did some of the first stuff on a web page that came up on there.

(Whereupon, Deposition Exhibit 78 was marked for identification.)

Q. Okay. And I'd like you to take a look at Exhibit 78, which is entitled "Replacement of Cinefilm with a Digital Archive and Review Network." It's Bates stamped PG15827 through 15834. I just enlarged it, and you can't see the numbers at the bottom of the page. Are you familiar with this article?

A. Yes.

Q. And I see your name on it. Did you draft this article?

A. Yes, along with Dr. Homes, who I mentioned before, and Marilyn Wondrow from the clinic.

Q. And was it published in the International Journal

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IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
SOUTHERN DIVISION

DATCARD SYSTEMS, INC., a California corporation,	Civil Action No. SACV10-1288 DOC(VBKx)
Plaintiff,	
vs.	(PER PROTECTIVE ORDER SECTION 11 THIS TRANSCRIPT HAS A TEMPORARY "CONFIDENTIAL-OUTSIDE COUNSEL ONLY" DESIGNATION FOR A PERIOD OF 14 DAYS AFTER THE DEPOSITION IS RECEIVED.)
PACSGEAR, INC., a California corporation,	
Defendant,	
AND RELATED COUNTERCLAIM	

DEPOSITION OF
ROBERT PETROCELLI
ASHAWAY, RHODE ISLAND
OCTOBER 3, 2011

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REPORTED BY: Paula T. Duran

FILE NO.: A5093C2

used for teaching purposes; and prior to recording media for that purpose for scientific talks, it was necessary that those images be anonymized. That any patient identifying information be expunged; and you have to replace it with something; so if you wanted to replace the patient's real name with a fictitious name, that was the opportunity to do that.

Q. Okay. So if the patient's name was Susan Smith, this allowed you to import different identifying information. You could put Jane Doe or John Doe, something like --

A. Right, before exporting a copy; that's correct. And then the other opportunity to do that before sending a copy over would be to correct an error before exporting it. That's probably not the best way to correct an error; but in practice, you might find some people who did it that.

Q. Okay. So if someone noticed that the patient's name was incorrectly spelled, they could correct it?

A. They should probably correct it with the administrative tools intended to do so, but you might find that people would be sloppy and do it that way.

Q. Okay. And what administrative tools are you talking about?

A. Oh, there's an entire suite of database

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administrative tools not covered in this manual that allow extensive editing of the demographic data and the database.

Q. Okay. If we could turn to Page 22 of Exhibit 202, this is -- it shows the dialog box entitled "Copy Study," do you see that?

A. Mm-hm.

Q. Okay. So at the very top it -- there's a choose a source box; correct?

A. Correct.

Q. Okay. This would, again, allow you to choose from any source, multiple databases, multiple workstations, to determine whether there was images relating to what you're looking for; correct?

A. Yes, you could chose from any source on that list. That's correct.

Q. Okay. And the list was, as we discussed earlier, plungeable(SIC)(phonetic) in terms that you could add all sorts of different sources to that list, different databases, and work stations; correct?

A. The list is -- consists of any of the types that we talked about, that's right.

Q. Okay. So it's not just the list shown here? This is just for example purposes?

A. Correct.

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Q. Okay. And then below the choose a source box, there's a display box, do you see that?

A. Mm-hm.

Q. So within there, you could choose the all button or choose those with button, and those with, there's a series of -- it looks like six different entries, narrowing devices, if you will, listed there?

A. Yes.

Q. So how does that -- if you wanted a -- all the studies from that source for Jane Doe, how would you do that?

A. This was partial completion searching, so you could type part of the name, so if you typed Jane, you would get everybody whose name started with Jane or Jane D-o or patient ID, you could type part of the patient ID. Similarly with procedure date, you could type everybody this month or everybody this year.

Q. Okay. Or could you put in a specific date if you knew it?

A. Of course, you could put in a specific date. Most commonly used would be patient ID or procedure physician because you typically are looking for the -- in a cath lab where there's an operator, in other words, someone pushing the catheter, and you typically order a cath by procedure physician. You don't just order a

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cath, you order a specific physician typically to do it. That would be the most typical way you would like for a case. You would like for your cases, so that's an important search field, and then the other final field there is study status. We have a notion of status in the system, open. I believe -- if I recall, the study status were open studies, which were studies that were still in progress, and we had a notion of studies that were archived; so once a study had been written to the next tier of storage, you would be able to know that a study had been completed and was already in the archive, so you knew that study was going to take longer to retrieve and there was a notion that was studied that was not open, but had been completed and was not yet archived.

Q. Okay. And then --

A. Let me correct that. There were three states.

Q. This is for a study status?

A. Study status. On-line, which was the study was immediately available, near line, I'm sorry, new, which means the study was newly available and had just been received, and then archived, which meant the study had been sent to the deep archive, and would require some delay in retrieval; so those reflected sort of the digestive system of the cath lab procedure.

Q. Okay. And this would be -- for example if it

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went to -- I wanted Enterprise servers, this is where you're talking about the higher Oracle storage devices?

A. And that maps the cath lab work flow fairly precisely. Studies new, it may actually still be in progress. Then it becomes on-line. It's no longer new. It's just out there and available for general consumption, and then eventually it migrates to an archive state after it ages for a certain amount of time. It may also go to an archive state to indicate that it has a CDR written for it, so it could occupy multiple states simultaneously; so for example, a state case could be both on-line and archived at the same time.

Q. Okay. And this was within what the -- what we discussed earlier when we were talking about archived would be perhaps a tape or CD recordable or on-line was a magnetic disk which was faster.

A. Right, but the value of the archives state and even in smaller systems would be -- allowed technologists to know if a CDR had yet been recorded; so for example if you were running in a lab that had no deep archive, but was only on-line storage, and CDR on the shelf was the means of archiving, one could see if one's fellow technologist had already written a CDR by merely looking at the status of their study; and if they saw OA, they could see that it was both on-line, and archived, which

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meant that a CDR had been recorded because the act of recording a CDR would add that status.

Q. Okay. So there would be some sort of --

A. If the system was configured to do that.

Q. Okay. And the Version 1.9 system had --

A. Most certainly because it was a very common use case for the smaller labs to still be using CDR for their shelf archive.

Q. And so this OA -- how would that come to the attention of the user at the DICOMview work station?

THE COURT REPORTER: The what, sir?

MR. HOLBROW: The user at the DICOMview work station.

A. OA is listed right in the study status list when you choose a study. You can see on this page.

Q. Okay. Okay. And so there would be some sort of internal tracking to determine whether a CD had already been burned on this -- relating to this image?

A. Yeah, that's what the "A" tells you. If you were in a lab with CDs only, then -- rather than keeping a paper log if a CD has been written, the "A" status will tell you if a CD's been written.

Q. Okay.

A. This in a sense predates the more complex logging we did later for HIPAA, in that it just allows

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you to do a simple track of whether you've written a CD or not, so it was a shorthand for technologists to keep track.

Q. Okay. And was there a way to determine when that CD was burned or who burned it or what machine burned this CD?

A. We did that later when we were asked by customers to develop HIPAA compliance.

Q. Okay. Okay. But the tracking system used in Version 1.9 would allow you to --

A. To know that had been done.

Q. Okay. Okay. And then still on Page 22, there's a box in the upper right-hand corner. It says choose a destination. This is where a selected image could be sent. Is that what choose a destination means?

A. Correct.

Q. Okay. And you could send it to a CD writer. You could send it to a variety of drives, databases. Again this -- does this relate to the dialog box we looked at on Page 36? We had a list of potential options?

A. Yeah, we called this the ability to copy from the left side to the right side, anywhere to anywhere, in our marketing literature; and basically, it would take the source and do whatever was necessary to put it in the

Page 40

appropriate format for the destination

Q. And in this case, there's one study shown in bottom box, Heartlab Demo ST?

A. Right. That's the study on that CD-ROM

Q. Okay, and that's the CD-ROM that's been selected in the choose a source. That's the study, and then if you -- that's the --

A. Looks like he's going to copy it.

Q. Okay. And he's going to copy it to the teaching share drive?

A. Right.

Q. Okay. And if instead, they had selected CD-writer, it would burn a copy of that image onto a CD?

A. Correct.

Q. If you can turn to Page 44 of Exhibit 202, Section 5.2 talks about CD Mastering. What is CD Mastering?

A. CD Mastering is the term for the process of recording CDR interchange media, and in this case in DICOM format.

Q. So these pages help explain what was going on on the previous page we were looking at in terms of clicking on copy and how it would burn to a CD?

A. Correct.

Q. Now, if you turn to Page 46, Section 5.2.1 talks

Page 41

about Self-Playing CDs? 11:00:03
A. Right. 11:00:04
Q. Explain what's meant by that? 11:00:05
A. Very early on back in 1995, when we were doing 11:00:10
DICK 95, we had talked about in the committee putting a 11:00:17
player on the CDR to allow the attendees at the meeting 11:00:20
to play back the images. Otherwise, they would just have 11:00:25
sort of a fancy paperweight. The timing for DISC 95 was 11:00:30
such that we just couldn't pull that off in enough time, 11:00:36
and we didn't want to give away our commercial software 11:00:40
on the player for obvious reasons; and so I believe on 11:00:44
DISC 96, one of the academic groups was contracted to do 11:00:49
that, and they actually pulled that off. What we decided 11:00:52
to do was, however, was to do something a little bit 11:00:55
better than that. We wanted -- 11:00:58
Q. I'm sorry. When you say "pull that off" with 11:00:59
DISC 96, you mean produce a disk with a viewing software? 11:01:01
A. They produced a disk with a viewing software on 11:01:03
it. 11:01:07
Q. Okay. 11:01:07
A. It was decided that it would be a lot of the 11:01:08
hospitals and doctors came to us, and said most of our 11:01:12
physicians don't have a way to look at these image if we 11:01:17
go filmless. We need a solution. They might have an old 11:01:20
film projector laying around, our CineProjector, when we 11:01:25

made film; and we can't afford to buy them a $50,000 work 11:01:27
station. They refer us a lot of business, but not that 11:01:33
much. Help, maybe we can by them a PC or something or 11:01:36
they have an office PC, so it became pretty clear that if 11:01:41
you could put a piece of software on the CDR that would 11:01:45
play for them, that would be a great thing; and if you 11:01:49
could make it as hassle-free as possible, that'd be even 11:01:51
better; so we put a piece of software on the CDR. Every 11:01:54
time it was published, there was a Windows program that 11:01:58
ran with auto-play, auto-run, which basically is a 11:02:01
feature of windows that tries to run a piece of software 11:02:05
when you insert a disk. I'm sure many of us are familiar 11:02:08
with that lovely feature; and it was basically a really, 11:02:12
really skinny down version of DICOMview that just had 11:02:16
some very basic play, stop, brightness, contrast, simple 11:02:19
capabilities; and it would only play the images that were 11:02:26
on the disk that it was on, and it was a great success; 11:02:29
and the other thing we did it is we put the logo of the 11:02:33
hospital right onto the little player. 11:02:38
Q. Okay. 11:02:41
A. So that when you burned the -- there was a 11:02:42
little resource file on there, so that when we customized 11:02:45
the installation for the customer, they would burn their 11:02:48
little CDR; and when you got a CDR from whatever hospital 11:02:51
it came from, it would immediately start up when you put 11:02:57

it in your PC with the player, and the little logo with a 11:03:00
hospital up in the corner of where that came from, so it 11:03:04
was great marketing for that hospital. 11:03:07
Q. Okay. Very good. 11:03:09
A. There were many imitators of this. I mean, at 11:03:10
the time everybody had their player. 11:03:12
Q. Okay. Let's -- getting back to Version 1.9 -- 11:03:14
A. Right. 11:03:21
Q. -- if I understand you correctly, someone 11:03:21
selects a resource that has images on it. Select an 11:03:25
image from that resource, and then they can hit copy 11:03:34
study, and that will burn onto the CD, and automatically 11:03:39
-- with the image, with the DICOM image, there'll be a 11:03:41
viewing program that will allow an any PC to view the 11:03:46
DICOM image? 11:03:51
A. Correct. 11:03:51
Q. Okay. I interrupted you. You said you weren't 11:03:52
alone. There was other people. 11:03:57
A. Sure. We were probably one of the -- we had 11:04:00
been doing this for a while before Version 1.9; and when 11:04:01
competitors realized that this was a good idea, I think 11:04:06
most of the companies, including some of the large ones 11:04:11
put some kind of a player on their disks, some of them 11:04:16
were good, and some of them weren't so good, but... 11:04:18
Q. Okay. And this player was the light version of 11:04:22

the DICOMview? 11:04:28
A. No, DICOMview Light was a different product 11:04:29
altogether. 11:04:31
Q. Okay. This was a scaled down version of the 11:04:32
DICOM? 11:04:34
A. Yeah, the player was it's own little program 11:04:34
that was derived from DICOMview. We used some of the 11:04:35
same source code to create it; but it was very, very 11:04:39
simple. 11:04:41
Q. Okay. 11:04:41
A. DICOMview Light was a different type of program 11:04:42
that could be given out by our referring hospitals that 11:04:45
was designed to be licensed differently. 11:04:48
Q. Okay. Okay. 11:04:51
A. Some of the marketing terms may have been used 11:05:04
interchangeably over the years, but the player was the 11:05:07
player. 11:05:10
Q. Okay. And you were -- you said were looking at 11:05:10
the user guide for 1.9. Unfortunately we don't have a 11:05:20
user guide for 1.7 or 1.8, but you said that your 11:05:24
recollection was that the viewing program that was 11:05:28
automatically added to burn CD's was part of -- was done 11:05:34
earlier than 1.9? 11:05:37
A. I can remember the request that came in from my 11:05:39
director of sales to add this feature, and it was one of 11:05:46

that they can be compliant with the mandate. There was no -- there were no daylight between that. 12:27:35 12:27:38
Q. Okay. If we can turn back to Page 22 of Exhibit 202 quickly, and just going to walk you through a scenario similar to the one we've previously discussed, but I just have a few other questions; so using the dialog box shown on Exhibit 202 of Page 22, which is also bate stamp page 24629, a user could choose a source; and that source could be, for example, Enterprise server? 12:27:41 12:31:10 12:31:17 12:31:18 12:31:22 12:31:29 12:31:36
A. Mm-hm. 12:31:41
Q. And the computer will have a network interface with that server; and based on the criterion in the display box find, for example, images relating to Jane Doe; correct? 12:31:42 12:31:47 12:31:53 12:31:59
A. Correct. 12:31:59
Q. And then it can choose any of those images in the choose study box and send them to the workstation's hard drive, for example? 12:32:00 12:32:08 12:32:15
A. Correct. 12:32:16
Q. Okay. And then it can, again, go to another workstation that might have -- act as a server in a database that has some images on it and search that database using a separate network interface to determine whether there's any images relating to Jane Doe again on that database; correct? 12:32:16 12:32:24 12:32:28 12:32:33 12:32:38 12:32:41

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A. Correct. 12:32:43
Q. And then any images and studies that are there would be shown in a choose a study box; correct? 12:32:43 12:32:48
A. Yes. 12:32:50
Q. And then you can select those, and send it to the same hard drive -- 12:32:50 12:32:55
A. Exactly. 12:32:57
Q. -- that you sent the earlier images that you got from -- about Jane Doe from the Enterprise server? 12:32:58 12:33:00
A. That's correct. 12:33:03
Q. And then you could choose that workstation hard drive that now contains both the images from the server and the other workstation, and choose those to have burned onto a CD? 12:33:03 12:33:08 12:33:13 12:33:18
A. That's correct. 12:33:21
Q. Okay. And when I say "those," I'm referring to the studies on Jane Doe that we received from the server, and then related studies that we received from the work- station? 12:33:21 12:33:26 12:33:30 12:33:33
A. That's correct. 12:33:34
Q. Okay. And those could all be burned onto a CD with the viewing software that's also mentioned in Exhibit 202 of Version 1.9 of the DICOMview? 12:33:34 12:33:39 12:33:42
A. That's correct. 12:33:47
Q. And all those images that we're talking about 12:33:47

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would be in the DICOM format? 12:34:24
A. Yes. 12:34:26
Q. Okay. And the viewing software would allow anyone that -- to view the images at any PC regardless of what other software it might have on it because the viewing software allows for the images to be viewed? 12:34:27 12:34:33 12:34:40 12:34:42
A. That's correct. 12:34:45
Q. Okay. And the other methodology of getting those selected and related images from Jane Doe onto a CD would be to -- instead of sending them to the hard drive each time, send them to the CD burner; and you're not sure whether the software could do that. It could send them but might not work effectively depending on how the CD was set up? 12:34:55 12:34:58 12:35:04 12:35:08 12:35:13 12:35:17 12:35:21
A. Yeah, I'm not sure what would happen when you sent that second case, whether that would multi session correctly – 12:35:22 12:35:24 12:35:27
Q. Right. 12:35:27
A. – especially back then in the 90s. 12:35:28
Q. Okay. 12:35:32
MR. HOLBROW: That's all I have. 12:36:16
MS. SMITH: I do have a few questions. 12:36:16
EXAMINATION 12:36:16
BY MS. SMITH: 12:36:16
Q. So you'd mentioned that DISC 96 and DISC 96? 12:36:27

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A. Correct. 12:36:31
Q. Okay. Do any copies of the DISC 95 or DISC 96 still exist? 12:36:31 12:36:35
A. I'm sure they do. In fact, the DISC 95 and DISC 96 were available for download for a long time; so they're probably still floating around in the Internet somewhere; and maybe some of the guys at Mayo or some of the other guys on the committees still have copies, so I'm sure they're obtainable 12:36:35 12:36:41 12:36:46 12:36:47 12:36:51 12:36:54
Q. Okay. Do you know of any documents that would describe what's on these disks? 12:36:57 12:37:02
A. The disk itself contained pretty extensive documentation; so if we went back and found the website, maybe using Wayback Machine that originally had the DISC 96 data published on it or 95, it was all selfdescibing stuff that was quite extensive read-me that went into some detail to what was on it. 12:37:04 12:37:09 12:37:13 12:37:17 12:37:21 12:37:25
Q. Okay. So that's the only documents that you're aware of? 12:37:26 12:37:28
A. Well, there was also extensive minutes of the DICOM committee that I'm sure were also published because DICOM was a working group of ACR-NEMA, American College of Radiology National Electrical Manufacturers Association; and I'm sure that they publish minutes as well leading up to that with respect to the DICOM project 12:37:29 12:37:32 12:37:34 12:37:39 12:37:41 12:37:41

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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
SOUTHERN DIVISION

DATCARD SYSTEMS, INC., a California corporation Plaintiff, v. PACSGEAR, INC., a California corporation Defendant. _______________ PACSGEAR, INC., a California corporation, Counter-Claimant, v. DATCARD SYSTEMS, INC., a California corporation, Counter-Defendant.	Case No. SACV 10-1288 DOC (VBKx) **DECLARATION OF OSMAN RATIB, M.D.** Courtroom of Judge Carter Date: February 13, 2012 Time: 8:30 a.m. Discovery Cut-Off: Dec. 23, 2011 Trial Date: April 17, 2012

DECLARATION OF OSMAN RATIB

I, OSMAN RATIB, declare as follows:

1. I have personal knowledge of the matters stated herein, and if called upon, could testify to them under oath. A copy of my CV is attached as Exhibit A.

2. I am currently Professor of Medicine, Chairman of the Department of Radiology and Head of the Division of Nuclear Medicine at the University Hospital of Geneva. I am a board certified Radiologist and Cardiologist.

3. I obtained my PhD in Medical Imaging from the University of California at Los Angeles ("UCLA") in 1989. My doctoral thesis focused on designing computer software that enabled a user to view and manipulate digitized medical images.

4. After earning my PhD, I returned to the University Hospital in Geneva where I directed the medical imaging section of the newly created Medical Informatics division.

5. In approximately 1993, I was a member of a group that developed a digital medical image viewing software program called Osiris, which was an extension of the work I did in connection with earning my PhD. We placed this software into the public domain for the benefit of the medical community.

6. In August 1996, the European Society of Cardiology ("ESC") held its Annual Meeting in Birmingham, England. The Annual Meeting is essentially a gathering of academics and members of industry from all over the world,

including the United States, to among other things, discuss and demonstrate advancements, including new products. At the Annual Meeting, I was involved with assisting with a demonstration of the Digital Interchange Standard of Cardiology. A summary of the tutorial prepared for the Annual Meeting and those involved with preparing it is attached as Exhibit B.

7. As part of the demonstration at the ESC Annual Meeting, I also assisted with creating a CD that contained: (i) the DISC Birmingham '96 Tutorial (discussed above); (ii) a collection of related medical images from multiple modalities for pseudo patient Jon Doe (e.g., x-ray, angiographic, ultrasound and nuclear medicine) and (iii) Osiris, the viewing program which allowed users to retrieve and display the DICOM images on any personal computer. (A brief summary of the European DISC '96 is attached as Exhibit C). We made thousands of these CDs and distributed them to attendees of the meeting to show the benefits of storing related DICOM images on CDs with viewing software.

8. In approximately 1998, I returned to UCLA where I as appointed Professor and Vice Chairman of the Department of Radiology. Part of my responsibilities included the deployment of an enterprise-wide strategy and infrastructure for image management and communication.

9. One of the projects we worked on at UCLA, beginning in approximately 1998, was a system which would allow a doctor or medical assistant to search for and select DICOM medical images from various databases

and then burn the images onto CDs along with the necessary software tools (i.e., Osiris), to allow someone to view the images on any personal computer.

10. The software was primarily developed at University Hospital of Geneva and we began using it at UCLA no later than fall 1999. The system included software and a workstation, which was networked to various databases and a CD burning device. Among other things, the system would:

a. Search for, retrieve and download DICOM image files from a PACS or any other networked database;

b. Sort and assemble images in corresponding studies and series;

c. Retrieve and match related data documents (reports, letters, etc.)

d. Burn the images and related data documents onto a CD-Rom with Osiris viewing software.

11. In order to accomplish the retrieval and collection of data documents related to an image study, we first caused the related documents to be stored on a database on the workstation's hard drive. Once the desired image studies were selected to be burned onto the CD, the software would search the database on the workstations' hard drive for related documents that matched an identifier associated with the selected study (e.g. accession number) and then burn any related data documents onto the CD, along with the selected studies and Osiris viewing software.

12. In short, the system we used at UCLA in 1999, could search for a study on a PACS database and/or a workstation's database, automatically locate related data documents and then burn the related data documents and selected studies onto a CD along with Osiris viewing software.

13. I described the above system in an article I wrote in 1999. That article was published in *Medical Imaging 2000: PACS Design and Evaluation: Engineering and Clinical Issues.* ("Article"). (Attached as Exhibit D). As shown in Figure 1 of the Article, the user would be provided with a dialog box which allowed them to choose the patient. Once the patient was identified, the user could choose the study and then a series within the study. Once the images were selected, the burn CD button could be clicked and at that point, the selected images and any related data documents would be burned onto a CD along with the viewing software.

14. We were using the system described in the Article at UCLA Medical Center, no later than fall 1999.

15. The system also allowed for labeling the disc. For example, the patient's name, studies, reports and the date were printed on the CD's label. A sample of a CD labeled with patient/study information relating to the content of the disc is shown in Figure 2 of the Article. The system was also designed to print the date the CD was created on the label. For example, the disc shown in Figure 2 was created using the above-described system at UCLA, on November 1, 1999, as stated on the disc.

16. As discussed above, the software and hardware combination described above was primarily tested and developed at the University Hospital of Geneva and used and further evaluated as a potential clinical tool at UCLA in 1999. For various reasons, we decided not to deploy the system clinically at UCLA. Nevertheless, this system was used at UCLA and created CDs at UCLA containing images and related data of real patients along with the Osiris viewing software, allowing the images to be viewed on any computer, no later than Fall 1999. There were no confidentiality restrictions in connection with the use of this system at UCLA and we subsequently prepared and published the associated Article in *Medical Imaging 2000.*

I declare under the penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed at Geneva, Switzerland on October __26_, 2011.

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IN THE UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

DATCARD SYSTEMS, INC., a California corporation, Plaintiff, v. PACSGEAR, INC., a California corporation, Defendant. ____________________ AND RELATED COUNTERCLAIM	Civil Action No. SACV10-1288 DOC (VBKx) **DATCARD SYSTEMS, INC.'S OPPOSITION TO PACSGEAR'S MOTION FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT OF THE "SEARCH/BURN" PATENTS** Date: February 13, 2012 Time: 8:30 a.m. Ctrm: 9D The Honorable David O. Carter

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Plaintiff DatCard Systems, Inc. ("DatCard") hereby opposes the Motion for Summary Judgment of Non-Infringement of the "Search/Burn" Patents filed by Defendant Pacsgear, Inc. ("Pacsgear").

I. INTRODUCTION

Pacsgear's position as to why it does not infringe the '174, '597, and '164 Patents is a house of cards precariously balanced on absurdly narrow constructions of a few claim terms. The bulk of the opening memorandum focuses on three claim terms, in particular: "related data," "medical data," and "related medical image data." Pacsgear proposes that each of these terms means the same thing — images, to the exclusion of all other kinds of data, including textual data. In Pacsgear's view, the MediaWriter cannot infringe the claims because it processes ***both*** images and textual data.

Pacsgear's constructions are incorrect as a matter of law. Most glaringly, Pacsgear ignores the basic tenets of claim construction and starts the construction process with the specification, instead of the claims themselves. After narrowing certain phrases in the specification to match example embodiments, Pacsgear next turns to the claims and plugs in the narrowing language to conclude that the claims are not infringed. Had Pacsgear started with the claims, instead of the specification, this pointless exercise could have been avoided. Related data, medical data, and related medical images data are all unambiguous, non-technical terms that are defined in the claims themselves. No construction is needed. Placed in context, related data and related medical image data mean data that is related to the selected medical image data. The term medical data is simply data that is data that is related to a patient. Pacsgear's MediaWriter clearly meets these features. Lacking any other viable basis for noninfringement, Pacsgear's house of cards collapses.

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II. LEGAL STANDARD

A. Summary Judgment

In considering a motion for summary judgment, a court views the evidence in the light most favorable to the nonmoving party and draws all justifiable inferences in favor of the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986). If reasonable minds could differ on disputed factual issues, summary adjudication is inappropriate. *Twentieth Century-Fox Film Corp. v. MCA, Inc.*, 715 F.2d 1327, 1329 (9th Cir. 1983).

B. Patent Infringement And Claim Construction

Determining patent infringement is a two-step process. *Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357, 1370 (Fed. Cir. 2010). First, the asserted patent claim must be construed as a matter of law. *Id.* Second, the properly construed claims must be compared to the accused product. *Id.* This second step is a question of fact. *Id.*

Claim construction "must begin with the words of the claims themselves." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1301 (Fed. Cir. 2006). When construing a claim, "the words of a claim 'are generally given their ordinary and customary meaning.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (*en banc*). And there is a heavy presumption that the ordinary meaning applies. *Epistar Corp. v. ITC*, 566 F.3d 1321, 1334 (Fed. Cir. 2009). If the ordinary meaning is unambiguous, and the patentee does not specially define the term in the specification or limit the term during prosecution, then the "the ordinary meaning of an unambiguous claim term controls." *Inverness Med. Switz. GmbH v. Princeton Biomeditech Corp.*, 309 F.3d 1365, 1371 (Fed. Cir. 2002).

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Statements in the specification only rise to the level of a "special definition" that narrows the scope of a claim in those rare instances where the patentee "demonstrated an intent to deviate from the ordinary and accustomed meaning of a claim term by including in the specification expressions of ***manifest exclusion or restriction***, representing a ***clear disavowal*** of claim scope." *Epistar*, 566 F.3d at 1334 (alteration removed) (emphases added). "If everything in the specification were required to be read into the claims, or if structural claims were to be limited to devices operated precisely as a specification-described embodiment is operated, there would be no need for claims." *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1121 (Fed. Cir. 1985) (*en banc*). Thus, absent a special definition, the claims of a patent are not limited by the examples given in the specification. *Ventana Med. Sys. v. Biogenex Labs., Inc.*, 473 F.3d 1173, 1181 (Fed. Cir. 2006). Even when there is only a single embodiment or example, the claims are not limited that embodiment. *Linear Tech. Corp. v. ITC*, 566 F.3d 1049, 1058 (Fed. Cir. 2009).

III. A REASONABLE JURY COULD, AND WOULD, FIND THAT MEDIAWRITER INFRINGES THE '174 PATENT

Pacsgear's position as to why it does not infringe the '174 Patent turns on very narrow constructions of the claim terms "related data," "database," and "automatically." Specifically, Pacsgear contends: (1) related data means only images, to the exclusion of all other kinds of data, including textual data, (2) database means a searchable collection of images, and only images, and (3) automatically means occurring without any user intervention whatsoever, not even a mouse click. Doc. 67 at 7, 20–21.

These constructions are incorrect as a matter of law. Rather, related data simply means data that is related to the selected medical image data. Database means any structured set of data held in a computer. To automatically search the database means to search the database such that, once the search is initiated,

the search function is performed by a machine, without the need for manually performing the function. Under the proper claim interpretation, Pacsgear's MediaWriter clearly meets these limitations.

Any reasonable jury would find that the MediaWriter literally infringes the '174 Patent, as explained in DatCard's co-pending motion for summary judgment of infringement. Furthermore, triable issues of fact remain regarding Pacsgear's liability for infringement under the doctrine of equivalents. Thus, Pacsgear has failed to carry its burden and is not entitled to summary judgment.

A. <u>Pacsgear's Construction Of "Related Data" Is Far Too Narrow</u>

Skilled artisans and laypeople alike understand the words "related" and "data." In fact, Pacsgear has never contended that the term is ambiguous or too technical to be understood by a lay jury. In the context of the claims, the ordinary and customary meaning of "related data" is clear: it is, simply, data that is related to the "selected medical image data."

Nevertheless, Pacsgear urges the Court to abandon the clear and unambiguous claim language and narrowly construe related data to mean images — and only images — to the exclusion of textual data, such as diagnostic reports. Pacsgear advocates this narrow construction because, in Pacsgear's view, the "specification consistently uses 'related data' to refer to image data." Doc. 67 at 15. Even if this were true, which it is not, this is simply not a basis for restricting claim scope. Accordingly, this Court should reject Pacsgear's proposed construction in favor of the clear and unambiguous language of the original claims.

1. Pacsgear's Construction Of "Related Data" Is Incorrect Because It Improperly Narrows The Claims To Cover Only Specific Embodiments In The Specification

Pacsgear correctly points out that the specification discloses embodiments in which "related data" are images. The law is clear, however, that claims

generally should not be narrowed to cover only specific embodiments disclosed in the specification. *See, e.g.*, *Linear Tech.*, 566 F.3d at 1058.

Moreover, the specification is entirely consistent with the ordinary and customary meaning of "related data" discussed above. The specification states that "[o]ne embodiment of the claimed system allows for searching ***medical exam data that are related*** and placing such data on the same CD." Ex. 265 at 2:14–17 (emphasis added).[1] The specification also discloses a viewing program that "allows users to read the patient demographics and ***exam information associated with the image data***" stored on the CD *Id.* at 4:24–26 "Medical exam data" plainly encompass more than just images and include text such as reports prepared by radiologists after completing their examination of the patient's images. *See* Doc. 63, Ex. 11 at 40–41; *see also* Ex. J at 56:9–10 ("In our PACS system, I'm used to thinking of exams as including reports.") In light of this broad language, the specification does not demonstrate the clear intent to disavow claim scope that is ordinarily required to restrict the scope of claims.

2. Pacsgear's Assertion That The Claims Would Be Invalid For Lack Of Enablement If Related Data Were Construed To Include Textual Data Is Unavailing

Pacsgear asserts that the claims "would be invalid if interpreted to include text data, because the patent does not enable the person of ordinary skill to practice it." Doc. 67 at 16 (citing *Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190 (Fed. Cir. 1999)); *see also id.* at 13 (citing *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1384 (Fed. Cir. 2001)). In other words, Pacsgear asserts that '174 Patent claims are not enabled

[1] Unless otherwise noted, all ***numbered*** exhibits were submitted by Pacsgear in Doc. 77. All cited ***lettered*** exhibits were submitted in Doc. 78.

(and therefore invalid) if the claims are construed to cover anything more than certain specific embodiments disclosed in the specification. Pacsgear glosses over the fact that there are broad embodiments covering "medical exam data" in general, which would include textual data and reports, as discussed above. In any event, this argument is nothing more than a thinly-veiled attempt by Pacsgear to circumvent Federal Circuit precedent, which strongly cautions ***against*** narrowing claims to cover only the specific embodiments in the specification. *See Linear Tech.*, 566 F.3d at 1058. Pacsgear's argument is unsupported by any evidence and is legally baseless.

Pacsgear cites no evidence, whatsoever, to support the contention that the '174 Patent would not have enabled the skilled artisan to practice an invention encompassing a search for textual data. *See* Doc. 67 at 16. Rather, Pacsgear relies solely upon attorney argument that, "in this case, the complete omission of language encompassing text data from the specification and figures provides no starting point from which a [person having ordinary skill in the art] can base his experimentation towards successfully practicing the invention." *Id.* This makes no sense. It is undisputed that the '174 Patent specification describes several examples of how to make and use a system that searches for related data, specifically related images in those examples. This is certainly a starting point from which the skilled artisan can successfully practice a search for other kinds of data, including textual data.

Furthermore, Pacsgear's contention is meritless in light of Pacsgear's lofty qualifications for the person of ordinary skill in the art. Specifically, Pacsgear argues that the ordinarily skilled artisan is a certified professional with five years of experience in designing and implementing PACS archives. *Id.* at 5. Given the detailed examples in the '174 Patent specification, Pacsgear cannot credibly suggest that this exceptionally qualified artisan would be wholly

unable to make and use a system that could search for related data, including both image data and textual data, after some minor experimentation.

Pacsgear's citations to *National Recovery* and *Karsten* do not support Pacsgear's novel proposition that claims are only enabled to the extent they are construed to precisely overlap embodiments in the specification. On the contrary, *National Recovery* reveals the folly of Pacsgear's proposition: that court observed that enablement encompasses not only "that which is disclosed in the specification," ***but also*** "the scope of what would be known to one of ordinary skill in the art without undue experimentation." 166 F.3d at 1196. *Karsten* has nothing to do with enablement. Rather, *Karsten* held that a court is not obligated to construe a claim to preserve its validity over prior art that was not considered during the original prosecution. 242 F.3d at 1384.

It is not surprising that Pacsgear grasps at straws for legal support. It is well established that the scope of the claims need only bear a "reasonable correlation" to the specification. *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1071 (Fed. Cir. 2005). "Enablement does ***not*** require the inventor to foresee every means of implementing an invention at pains of losing [the] patent franchise. . . . Such narrow patent rights would rapidly become worthless as new modes of practicing the invention developed, and the inventor would lose the benefit of the patent bargain." *Id.* (emphasis added).

Accordingly, this Court should reject Pacsgear's attempted end run around the well-established rules of claim construction.

3. Pacsgear's Criticisms Of Datcard Are Unwarranted And Do Nothing To Inform The Proper Construction Of The Claims

Pacsgear correctly points out that the file history is silent on the scope of the term related data. Doc. 67 at 16. Incredibly, however, Pacsgear blames DatCard because the file history does not support Pacsgear's desired construction: "DatCard had the luxury of designing its claims in an attempt to

entrap the MediaWriter, but never gave any hint to the Patent Office that text data was included . . . ." *Id.* If Pacsgear is contending that a patent applicant must explain to the Patent Office all possible product features that a claim term might cover when the patent issues, Pacsgear provides no support for it. DatCard is not aware of any such duty.

This attack on DatCard is completely unwarranted and irrelevant to the proper interpretation of the claims. It serves only to cast DatCard as a wrongdoer, when DatCard has done nothing wrong

4. Pacsgear Mischaracterizes Dr. Rowberg's Testimony Regarding The Term Related Data

Finally, Pacsgear contends that "Dr. Rowberg . . . admitted that the 'related data' was limited to medical image data." *Id.* (citing Ex. J at 119:17–121:1.) Pacsgear mischaracterizes Dr. Rowberg's testimony. Dr. Rowberg explained that, where the phrase related data is recited in certain examples ***in the specification***, the phrase refers to images. Dr. Rowberg never contended that the ***claim term*** "related data" is limited to images, however. *See* Ex. J at 120:18–121:1.

Rather, Dr. Rowberg correctly distinguished between specific examples of related data in the specification and the use of that term in the claims. As explained above, in light of the broad language elsewhere in the specification, the specification does not demonstrate any intent, let alone clear intent, to disavow claim scope that is required to restrict the scope of the claims. *See Epistar*, 566 F.3d at 1334.

In any event, Dr. Rowberg and Dr. Horii do not have special expertise in the meaning of common, non-technical terms like related data. The Federal Circuit attributes little or no weight to expert testimony where the disputed term has no specialized meaning in the art. *Sinorgchem Co. v. ITC*, 511 F.3d 1132, 1137 n.3 (Fed. Cir. 2007) (Without evidence that those skilled in the art would

recognize a term in the specification to have an accepted meaning in the art, "testimony as to how one skilled in the art would interpret the language in the specification is entitled to little or no weight."); *see also AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1053 (Fed. Cir. 2010) (The Federal Circuit "generally views expert testimony as less reliable than the patent and its prosecution history in determining how to read claim terms.") (internal quotation marks omitted). Accordingly, Dr. Rowberg's and Dr. Horii's testimony regarding the interpretation of an unambiguous claim terms like related data is entitled to little, if any, weight.

B. <u>Pacsgear's Construction Of Database Depends On Pacsgear's Construction Of Related Data And Is Improperly Narrow For The Same Reasons</u>

Everyone understands what database means. The Oxford Dictionary defines database as "a structured set of data held in a computer." Doc. 66-5 at 3. There is a heavy presumption that this ordinary and customary meaning applies to the claim. *See Epistar*, 566 F.3d at 1334. Furthermore, in both the claims and the specification, "database" is an ordinary word, used in its ordinary sense and consistently with the dictionary definition. *E.g.*, Ex. 265 at 3:65–4:2, 6:1–15, 6:53–59.

Relying solely on Dr. Horii's personal opinion, Pacsgear contends that, "according to the conventional technical definition," the claim term database means "the electronic collection of image data stored in a way to allow for easy search and retrieval following the request of a user." Doc. 67 at 7:23–25. In Pacsgear's view, the collection must be of images, and only images, and the images must be "searchable." This is hardly a conventional definition of database. In fact, Dr. Horii testified that, before he became involved in this case, he did not understand the word database to mean a collection of ***images***, specifically. Rather, he testified that he understood the term database to simply

mean a "collection of elements, organized to allow for searching." Stewart Decl., Ex. 1 at 234:21–235:21.

Dr. Horii pieced together Pacsgear's narrower definition by importing words from other claim elements and from the specification (like "search" and "image data") and plucking other words from thin air (like "following the request of a user"). *See* Doc. 67 at 7. As a result, it takes Dr. Horii more than twenty words to define the single word database. Moreover, although the logic of Dr. Horii's construction is extremely difficult to follow, Pacsgear admits that the construction is based on the fundamental assumption that related data "explicitly excludes text reports." *Id.* As explained above, this assumption is flawed. The proper construction of related data encompasses data in general, both image data and textual data. Without this flawed assumption to provide a base, Pacsgear's construction completely collapses.

The specification also proves that Pacsgear's construction is unsound. As Dr. Horii admits, in the specification, the term database expressly encompasses ***both*** image and textual data storage. *E.g.*, Ex. 265 at 3:65–4:2, 6:1–15, 6:53–59; *see* Ex. B at 6. For instance, the specification describes "database" as encompassing "audit records." Ex. 265 at 6:53–59. These audit records can include textual data, such as physician and patient names. *Id.* Moreover, according to the specification, a database is not necessarily "searchable at a user's request." For example, the specification never states that the database is "searchable" for audit records, and it certainly never states a database is searchable at a user's request. Yet, it is still a database. In light of the specification, Pacsgear's overly complicated construction makes no sense.

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C. <u>Pacsgear's Construction Of "Automatically" Defies Not Only Its Ordinary Meaning, But Also A Fundamental Tenet Of Claim Construction</u>

Pacsgear acknowledges that the parties dispute the proper interpretation of the claim term "automatically." Doc. 67 at 16. DatCard contends that "automatically" means: "once initiated, the function is performed by a machine, without the need for manually performing the function." *See* Doc. 65 at 13. Pacsgear proposes a far narrower construction of this term and contends that automatically should mean occurring without any "user intervention" whatsoever. Doc. 67 at 17, 20. In Pacsgear's view, the patent is avoided if a "user must intervene on multiple occasions before the search for related data occurs . . . (e.g., position cursor and clicking the mouse to select studies, position the cursor and clicking the Burn button, select whether or not reports should be included, click the Confirm button, etc...)." *Id.* at 21–22 (second ellipsis original). Pacsgear's construction is inconsistent with the ordinary meaning and, furthermore, violates a basic tenet of claim construction.

In *CollegeNet, Inc. v. ApplyYourself, Inc.*, 418 F.3d 1225, 1235 (Fed. Cir. 2005), the Federal Circuit considered the proper construction of "automatically" in a computer-implemented method. In that case, the competing constructions were almost identical to the constructions proposed here. The defendant proposed a very narrow construction similar to Pacsgear's, arguing that automatic means "a process that occurs ***without human intervention***, such that a human does not have the option to intercede and alter the flow of that process." *Id.* (emphasis in original). The plaintiff, like DatCard here, argued that automatically means that, "***once initiated***, the function is performed by a machine, without the need for manually performing the function." *Id.* (emphasis in original). Consistent with the latter construction, a user may initiate an automatic search by selecting the parameters for the search and

confirming that a search should be conducted.

The Federal Circuit found the latter construction to be correct. *Id.* The Federal Circuit observed that automatic processes still have some amount of user intervention:

> Simply because a human has to load an automatic dishwasher and press the start button, and has the ability to turn it off mid-cycle, does not mean that the device does not "automatically" wash the dishes. Similarly, an "autopilot" which is turned on by a human and necessarily must be able to be interrupted by a human once the automatic process is engaged remains an "automatic" device.

Id. (internal quotation marks, citations, and alterations removed for clarity). Likewise, it is ordinarily understood that an automatic search is still automatic, even if a user has to first confirm certain settings and press the start button.

This construction of automatically also comports with a fundamental tenet of claim construction. In *CollegeNet*, the claim at issue used the "inclusive or open-ended" transitional word "comprising" in the preamble. 418 F.3d at 1227–28, 1235 (reciting a "method of creating and processing [forms] over a computer network . . . comprising"). The Federal Circuit found that "the use of 'comprising' suggests that additional, unrecited elements are not excluded. Such elements could include human actions to expressly initiate the automatic [computer functions], or to interrupt such functions." *Id.* at 1235. Claims 1 and 8 of the '174 Patent also use the open-ended transitional word "comprising" in their preambles. Ex. 265 at 9:25 (a "system comprising"), 10:11 (a "method comprising"). Thus, the claims contemplate that users may take additional, unrecited actions, such as confirming the user selection and initiating the search.

Pacsgear's proposed construction, which improperly excludes unrecited user actions, is incorrect as a matter of law. Instead, in the context of the '174 Patent claims, "automatically search the database" means "search the database

such that, once initiated, the search function is performed by a machine, without the need for manually performing the function."

D. <u>Under The Proper Interpretation Of Related Data, Database, And Automatically, A Reasonable Jury Would Find The Claims Literally Infringed</u>

Pacsgear's noninfringement arguments depend on Pacsgear's absurd constructions of the claim terms related data, database, and automatically, in the second and fourth elements of claims 1 and 8. Because Pacsgear's constructions are meritless, so are the distinctions that Pacsgear attempts to draw.

In DatCard's Memorandum of Points and Authorities in Support of DatCard's Motion for Summary Judgment of Infringement of U.S. Patents 7,783,174 and 7,734,157 (Doc. 65), DatCard details precisely how Pacsgear's customers using at least one other browsing terminal per Pacsgear's instructions satisfy every element of claim 1 of the '174 Patent. *Id.* at 5, 7–11, 14–15. Claim 8 is very similar to claim 1, except that it eliminates the "plurality of browsing terminals" limitation and, instead, adds a "labeling" limitation. Pacsgear does not dispute that the MediaWriter satisfies the recited labeling limitation. DatCard's memorandum establishes literal infringement and more than suffices to defeat Pacsgear's motion for summary judgment.

E. <u>Triable Issues Remain Regarding The Doctrine Of Equivalents</u>

Pacsgear attempts to dispose of the issue of infringement under the doctrine of equivalents in a single sentence. Pacsgear asserts, in a conclusory fashion, that there "can be no infringement by equivalence of the '174 Patent, because . . . a system which searches multiple databases versus a single database, searches for text reports instead of images and requires user intervention as opposed to occurring 'automatically' - performs a substantially different function in a substantially different way to achieve a substantially different result." Doc. 67 at 22. Pacsgear offers no evidence to support this

bald attorney argument. DatCard's expert, Dr. Rowberg, disagrees with Pacsgear and has detailed why he disagrees in his expert report. *See* Ex. C at 60–61, 70–71. At the very least, Dr. Rowberg has raised a triable issue of fact. *See Abraxis Bioscience, Inc. v. Mayne Pharma (USA) Inc.*, 467 F.3d 1370, 1379 (Fed. Cir. 2006) ("infringement under the doctrine of equivalents is a factual determination"). Because reasonable minds could certainly differ on this factual issue, summary adjudication is inappropriate.

IV. A REASONABLE JURY COULD FIND THAT MEDIAWRITER INFRINGES THE '597 PATENT

Once again, Pacsgear perches is arguments regarding noninfringement for the '597 Patent on tortured constructions of (1) medical data and (2) automatically. Mirroring the proposed constructions for related data and automatically in the '174 Patent, discussed above, Pacsgear contends: (1) medical data means only images, to the exclusion of all other kinds of data, including textual data, and (2) automatically means occurring without even so much as a user's mouse click. Doc. 67 at 15–17.

Pacsgear's constructions are incorrect for the same reasons discussed above in the context of the '174 Patent. Medical data means medical data that is related to a patient, as stated unambiguously in the claims themselves. Ex. 263 at 9:24–26, 10:7–9 (reciting a "computer-implemented method" and a "system" "for automatically generating a portable computer-readable medium containing ***medical data related to a patient***") (emphasis added). Automatically means that, once initiated, a function is performed by a machine, without the need for manually performing the function. Pacsgear's MediaWriter clearly meets these limitations, and Pacsgear provides no other bases to support noninfringement.

Applying the proper interpretations of the '597 Patent claims, a reasonable jury would find the claims to be infringed. Furthermore, triable issues of fact remain regarding Pacsgear's liability under the doctrine of

equivalents. Thus, Pacsgear has failed to carry its burden in the present motion, and Pacsgear is not entitled to summary adjudication as to the '597 Patent.

A. <u>Pacsgear's Construction Of Medical Data Is Incorrect Because It Limits Claim Scope To Cover Only Specific Embodiments In The Specification</u>

"Medical data" is not a term of art, and it is not ambiguous. Any layperson can read it and understand it. In fact, the claims expressly define it. Because the meaning of medical data is clear on its face, and the specification does not specially define medical data using words of manifest exclusion or restriction, there is no need to delve into the specification, file history, and extrinsic evidence to ascertain its meaning. *See Inverness*, 309 F.3d at 1372 ("the ordinary meaning of an unambiguous claim term controls" unless the patentee specially defines the term in the specification so as to clearly disavow claim scope or the patentee limits the term during prosecution). This claim term simply does not require construction.

Nevertheless, Pacsgear contends that medical data should be construed to mean images — and only images — to the exclusion of any other data, such as textual reports. Again, Pacsgear improperly couches this narrow construction in certain passages from the specification. Doc. 67 at 15–16.

Pacsgear's construction in the context of the '597 Patent claims is flawed for the same reasons discussed above with respect to the '174 Patent. First and foremost, the construction defies Federal Circuit precedent and redefines unambiguous claim language to cover only specific embodiments disclosed in the specification. *See Linear Tech.*, 566 F.3d at 1058. Second, the construction is flatly inconsistent with other portions of the specification discussing related "medical exam data" and associated "exam information" more generally. Ex. 263 at 2:14–17, 4:25. Thus, Pacsgear's construction is meritless.

/ / /

1. Pacsgear Provides No Evidence That The Meaning Of Medical Data Is Ambiguous

Pacsgear attempts to somehow justify the needless construction exercise by stating that "Rowberg testified that such claim terms were ambiguous, therefore necessitating reliance on the specification." Doc. 67 at 15 (citing Ex. J at 65:3–25.) As the Court can read for itself, Dr. Rowberg testified to no such thing. At most, Dr. Rowberg testified that medical data is not a term of art:

> Q. And is there anything in the patent that would suggest that this term ["medical data"] means anything but images?
>
> A. The fact that it's a different phrase.
>
> Q. Okay.
>
> A. At least makes me wonder. And it is not specific as I would have liked to see in a document.
>
> Q. Okay. ***So you aren't sure what it means?***
>
> A. And I almost wonder if it's a legal term instead of a medical term because it's out of my normal vocabulary.

Ex. J at 65:15–25 (emphasis added). Clearly, nothing in the colloquy cited by Pacsgear supports a conclusion that Dr. Rowberg believes the claim term medical data to be ambiguous. That "testimony" came from Pacsgear's counsel, not Dr. Rowberg. In any event, Pacsgear's expert has suggested that the term medical data is ***not*** ambiguous. Specifically, Dr. Horii testified that, before he became involved in this case, he understood medical data to simply mean "[a]nything related to patient care." Stewart Decl., Ex. 1 at 190:1–5. Evidently, no one but Pacsgear finds the term medical data to be ambiguous.

2. Pacsgear Mischaracterizes Dr. Rowberg's Testimony Regarding The Construction Of The Term Medical Data

Finally, Pacsgear contends that Dr. Rowberg "also conceded that medical data is synonymous with medical image data and would not include text

reports." Doc. 67 at 16 (citing Ex. J at 69:3–7.) Once again, Pacsgear mischaracterizes Dr. Rowberg's testimony. Dr. Rowberg actually testified:

> Q. Okay. And ***if, as we discussed, "medical data" is defined to be synonymous with "medical image data,"*** then that would not include text reports, correct?
>
> A. Correct.

Ex. J at 69:3–7 (emphasis added). Agreeing to the logical consequences of a hypothetical definition proposed by Pacsgear's counsel hardly qualifies as conceding that the claim term medical data is synonymous with images.

In any event, even assuming that Dr. Rowberg had opined that the claim term medical data would not include text reports, expert testimony regarding the construction of an unambiguous claim term like medical data is entitled to little, if any, weight. *See Sinorgchem*, 511 F.3d at 1137 n.3; *AstraZeneca*, 633 F.3d at 1053. Dr. Rowberg and Dr. Horii have no special expertise in the meaning of non-technical terms like medical data.

In conclusion, in the context of the '597 Patent claims, medical data is, simply, medical data related to a patient. It requires no construction. Pacsgear's effort to rewrite the claims has no basis in law or in fact and is nothing more than a blatant attempt to shirk liability for infringement.

B. <u>Pacsgear's Construction Of "Automatically" Is Incorrect For The Same Reasons Discussed For The '174 Patent</u>

Pacsgear proposes the same construction for the term automatically in the '597 Patent that it proposed for the '174 Patent. For the same reasons discussed above, Pacsgear's proposed construction is flawed, and "automatically" means that, "once initiated, the function is performed by a machine, without the need for manually performing the function."

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C. <u>Applying Proper Interpretations Of Medical Data And Automatically, A Reasonable Jury Would Find The Claims Literally Infringed</u>

After studiously rewriting the claims to include additional limitations that simply are not there, Pacsgear conveniently concludes that no reasonable jury could find the claims infringed. Doc. 67 at 17–20. Once again, this house of cards depends entirely upon Pacsgear's flawed constructions. Without these constructions, the house of cards collapses.

As Dr. Rowberg explained in his initial expert report, when a MediaWriter user submits a request for a patient's medical data, the MediaWriter will automatically search a first computer database (a PACS or imaging modality) for a first set of medical imaging data (images) related to the patient, based on the request. Ex. C at 42–43, 48 (citing, *e.g.*, Doc. 66-3 at PG006759–60; Doc. 66-4 at PG006799–800). When the "Include Reports" option is selected, the MediaWriter also automatically searches a second computer database for additional medical data (diagnostic reports) also related to the patient. For example, the MediaWriter can search the MediaWriter's local drive for "HL7"-type reports, and it can search a report broker for "Mitra"-type reports. *Id.* at 44–45, 49–50 (citing, *e.g.*, Stewart Decl., Ex. 2 at PG009418; Stewart Decl., Ex. 3 at PG015448; Stewart Decl., Ex. 4 at 31:14–23, 34:8–35:3, 47:23–48:13.) Then, the MediaWriter automatically generates a CD or DVD with (1) the patient's images recorded in a standard medical imaging format (DICOM), and (2) the additional related diagnostic reports. *Id.* at 46–47, 53. (citing Doc. 66-3 at PG006755–56; Doc. 66-4 at PG006795–96; Doc. 66-2 at 25:24–26:24, 29:7–14, 65:10–16). These facts cannot be disputed.

Pacsgear complains that "DatCard has failed to provide any evidence demonstrating that anyone has used the MediaWriter to conduct, via the Configure Reports option, a search of a second PACS or modality for medical

images . . . ." Doc. 67 at 18 (citing *Standard Havens Prods. v. Gencor Indus.*, 953 F.2d 1360, 1374 (Fed. Cir. 1991)). Pacsgear's complaint is premised on the assumption that both the first and second databases ***must*** be a PACS or imaging modality to meet the claims. This assumption is incorrect. Report brokers, and even the MediaWriter's local drive, are also databases within the scope of the properly construed claims. And DatCard has ample evidence that customers are using these databases. Clearly, all of Pacsgear's customers connect their MediaWriters to PACS archives or imaging modalities. *See* Doc. 66-3 at PG006759–60; Doc. 66-4 at PG006799–800; *see also* Stewart Decl., Ex. 1 at 246:18–247:7 (explaining that a MediaWriter without a PACS or modality is little more than an "anchor" or "desk decoration"). Furthermore, Brian Cavanaugh testified on behalf of Pacsgear that at least five customers use HL7 reports. Stewart Decl., Ex. 4 at 60:20–61:9. Pacsgear's customer service logs also show that Pacsgear's customers are also using report brokers that store reports in a separate database. Stewart Decl., Ex. 5.

The '597 Patent claims are not complicated. Pacsgear only makes them seem complicated with elaborate and erroneous claim constructions. Without these constructions, Pacsgear's noninfringement arguments collapse, and Pacsgear cannot establish that a reasonable jury would not side with DatCard and find the '597 Patent claims to be infringed.

D. <u>Triable Issues Remain Regarding Infringement Under The Doctrine Of Equivalents</u>

In Pacsgear's one-sentence "analysis" of the issue of infringement under the doctrine of equivalents, Pacsgear blithely contends that if the MediaWriter does not literally infringe the claims, there is no infringement under the doctrine of equivalents. Doc. 67 at 20. ("There can be no infringement by equivalence of the '597 patent, because . . . [t]here is no automatic search for unselected image data nor is image data obtained from two databases.") This is incorrect. It is

well established that literal infringement and infringement under the doctrine of equivalents are distinct issues. *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21, 117 S. Ct. 1040, 137 L. Ed. 2d 146 (1997). Infringement under the doctrine of equivalents is a question of fact for the jury. *Abraxis*, 467 F.3d at 1379.

Pacsgear offers no evidence, whatsoever, to support its bald attorney argument. This is not enough to carry Pacsgear's initial burden. *See Nissan Fire & Marine Ins. Co. v. Fritz Cos.*, 210 F.3d 1099, 1105 (9th Cir. 2000) (In a motion for summary judgment, a "moving party may not require the nonmoving party to produce evidence supporting its claim . . . simply by saying that the nonmoving party has no such evidence.") In light of Pacsgear's complete failure of production, summary judgment is inappropriate.

V. A REASONABLE JURY COULD FIND THAT MEDIAWRITER INFRINGES THE '164 PATENT

Pacsgear's noninfringement arguments for the '164 Patent are largely the same as those for the '174 and '597 Patents, discussed above. Specifically, Pacsgear relies upon a narrow construction of the claim term "related medical image data." For claim 16 and its dependents, Pacsgear also relies upon a narrow construction requiring the final two method steps to be performed in sequential order, such that the penultimate step completes before the ultimate step begins. These constructions are flawed and cannot carry Pacsgear's burden on this motion. Several factual issues remain for a jury to resolve, including Pacsgear's infringement under the doctrine of equivalents.

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A. Yet Again, Pacsgear's Improperly Narrows "Related Medical Image Data" To Cover Only Specific Embodiments In The Specification

The '164 Patent claims are very clear. They are not filled with terms of art. Because the claim term related medical image data is consistently defined in the claims themselves to mean data that is related to the selected medical image data, it is facially unambiguous. *See* Ex. 262 at 619 col.1 ll.35–37, 62–64 ("a search module configured to search the database for related medical image data that is related to the selected medical image data"), 619 col.2 ll.23–25 ("searching the database for related medical image data that is related to the selected medical image data"). There is no need to construe an unambiguous claim limitation. *Inverness,* 309 F.3d at 1372.

Pacsgear claims that Dr. Rowberg's "construction must be ferreted out from his invalidity and infringement reports." Doc. 67 at 8. The Court need not "ferret" very long. Dr. Rowberg states: "I believe that the term 'related medical image data,' in the context of the claims, is clear and unambiguous." Doc. 63, Ex. 11 at 8. "Thus, in my opinion, related medical image data is, as the claims state, data that is related to the selected medical image data." *Id.* at 8–9. Applying the ordinary claim language, Dr. Rowberg concluded that related medical image data encompasses images and text such as reports. Ex. C at 22.

Pacsgear accuses Dr. Rowberg of retreating from his original claim interpretation during his deposition and would have this Court believe that Dr. Rowberg now sides with Pacsgear's constructions. *See* Doc. 67 at 8–10. This is completely untrue. At his deposition, Dr. Rowberg agreed with Pacsgear that written reports are not literally recited in the specification and that, in example embodiments, related medical image data are images. He did not agree that the '164 Patent ***claims*** are limited to images, and only images. Pacsgear's memorandum obfuscates this distinction. In any event, even if Dr. Rowberg had opined that the claim term related medical image data would not encompass

text reports, which he did not, Dr. Rowberg has no special expertise in the meaning of unambiguous, non-technical terms, so his testimony is entitled to little weight. *See Sinorgchem*, 511 F.3d at 1137 n.3; *AstraZeneca*, 633 F.3d at 1053.

As DatCard has explained in this opposition — repeatedly — Pacsgear's claim construction is improper because it starts with the specification, when it should have started with the claims. *See Amgen*, 457 F.3d at 1301. Because related medical image data is defined in the claim, this term is facially unambiguous and there is no need to decipher another meaning from the specification. Furthermore, it is legally "improper to add a . . . limitation to the claims at issue where none appears." *Laryngeal Mask Co. Ltd. v. Ambu A/S,* 618 F.3d 1367, 1371 (Fed. Cir. 2010) ("The patentee is entitled to the full scope of his claims, and we will not limit him to his preferred embodiment or import a limitation from the specification into the claims.")

Following the express claim language, instead of Pacsgear's improperly narrow constructions culled from example embodiments, Dr. Rowberg found the claims to be literally infringed and infringed under the doctrine of equivalents. Ex. C at 16–41. His testimony creates a triable issue of fact for a jury. On this record, summary adjudication for Pacsgear is inappropriate.

B. <u>The Final Two Steps Of Claim 16 Are Not Sequential, And Pacsgear Cannot Avoid Liability On This Basis</u>

Pacsgear contends that the MediaWriter does not infringe claim 16 because its "inkjet head" does not "(i) print a label and ***then*** (ii) affix it to the CD." Doc. 67 at 14. Pacsgear cites nothing to support this narrow construction.

Claim 16 actually recites "printing a label using the production station, wherein the label includes identifying information associated with the selected medical image data; and affixing the label to the data storage medium using the production station." Ex. 262 at 619 col.2 ll.38–42. The word "then" is simply

not there. Pacsgear placed it there under the guise of claim construction as a last-ditch effort to avoid infringement.

Pacsgear's construction is meritless, as the law and facts are squarely against Pacsgear. "Unless the steps of a method actually recite an order, the steps are not ordinarily construed to require one." *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1342 (Fed. Cir. 2001). Rather, a limiting construction is only adopted when "the language of the claim, the specification and the prosecution history" would support it. *Id.* Here, none of these support Pacsgear. First, as explained above, claim 16 does not say that the label is applied to the data storage medium ***after*** the label is printed. Second, the file history is altogether silent on labeling. Third, each time the specification discusses labeling, the discussion is — without exception — in the context of a label printed directly on a CD. Doc. 62-4 at DAT078177 col.6 ll.36–37 ("printed by the target production station as a label on the top of each CD produced"), DAT078178 col.7 ll.1–4 (the production station "prints a label on top of every CD"), DAT078178 col.8 ll.14–17 (the production station produces CDs "with labels printed on top of the CDs"). Requiring the final two steps to be sequential is inappropriate because it would be inconsistent with the specification. Pacsgear simply cannot defeat the presumption that there is no particular order to the last two method steps.

Dr. Rowberg explains in his initial report that Pacsgear's MediaWriter includes a "built-in medical label printer" that prints and affixes a label. Ex. C at 37–38. Furthermore, Pacsgear cannot and does not deny that a label is, in fact, printed on and affixed to the CD's product by the MediaWriter. Pacsgear only disputes that activating the printer's "inkjet head does not constitute 'printing a label.'" Doc. 67 at 14. Even assuming the distinction somehow provides Pacsgear a viable basis for noninfringement, Pacsgear failed to cite a shred of evidence to support it. A reasonable jury could certainly disagree with

Pacsgear's bald attorney argument in light of Dr. Rowberg's evidence.

In conclusion, Pacsgear is not entitled to summary adjudication on literal infringement for the '164 Patent.

C. Triable Issues Remain Regarding Infringement Under The Doctrine Of Equivalents

Pacsgear states, in a completely conclusory fashion, that the MediaWriter does not satisfy the so-called "function-way-result" test for equivalence because it does not literally include certain features recited in the '164 Patent claims. Once again, Pacsgear conflates literal infringement and infringement under the doctrine of equivalents in an effort to dispense of the equivalence issue without meaningful analysis. Pacsgear's approach is contrary to the basic law of equivalence. *See Warner-Jenkinson*, 520 U.S. at 21.

Furthermore, Pacsgear has offered no real evidence of noninfringement under the doctrine of equivalents. At best, Pacsgear provides a single citation to Dr. Horii's rebuttal report. Doc. 67 at 13 (citing Ex. B at 15). However, Dr. Horii's entire "analysis" of equivalence is this: "In my opinion, a system which searches multiple databases versus a single database performs a substantially different function in a substantially different way to achieve a substantially different result." Ex. B at 15. This is not evidence. It is just a conclusory recital of the "function-way-result" test.

Dr. Rowberg has opined in writing that, if literal infringement is not found, there are several equivalent elements between the '164 Patent claims and the MediaWriter. Ex. C at 16–41. In light of the meager "evidence" offered by Pacsgear, Dr. Rowberg's testimony raises a triable issue for the jury. *See Abraxis*, 467 F.3d at 1379 (infringement under the doctrine of equivalence is a question of fact). Summary adjudication of this issue is inappropriate.

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VI. CONCLUSION

Pacsgear's motion for summary judgment simply layers bald attorney argument and irrelevant accusations upon heavily flawed claim constructions. Because it lacks even the most rudimentary evidentiary basis, Pacsgear's motion completely collapses in the face of the basic rules of claim construction. Pacsgear has not carried its burden for summary judgment, and the motion should be denied.

Respectfully submitted,

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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
SOUTHERN DIVISION

DATCARD SYSTEMS, INC., a California corporation Plaintiff, v. PACSGEAR, INC., a California corporation Defendant.	Case No. SACV 10-1288 DOC (VBKx) **MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO DATCARD'S MOTION FOR SUMMARY JUDGMENT RE INFRINGEMENT OF U.S. PATENT NOS. 7,783,174 AND 7,734,157**
PACSGEAR, INC., a California corporation, Counter-Claimant, v. DATCARD SYSTEMS, INC., a California corporation, Counter-Defendant.	Courtroom of Judge Carter Date: February 13, 2012 Time: 8:30 a.m. Discovery Cut-Off: Dec. 23, 2011 Trial Date: April 17, 2012

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I. INTRODUCTION

Both DatCard and Pacsgear are moving for summary judgment regarding infringement of the '174 Patent- albeit in different directions. The parties generally agree on the way the MediaWriter works but disagree on the meaning and scope of several claim terms.

In order to satisfy its burden of proving infringement, DatCard asks the Court to construe the claims so broadly they defy reason, common sense and the patents' specification. For example, DatCard contends that "database" means just about anything including an unsearchable buffer location and that a buffer location on a hard drive and a file system constitute the same database.

DatCard also contends that "related data" is unambiguous because "skilled artisans and lay people alike understand the words "related" and "data" (DC[1] Brief p. 13). In doing so, they ignore their own expert who testified that the terms did not have a clear and ordinary meaning in the medical environment. When asked whether "related data" was synonymous with "related medical image data" he replied:

> "….And because these terms are not on the tip of our tongue in the medical environment, I don't have a visceral feeling about the nature of that qualification. But at this point I am concerned that "related data" is probably broader and may include any type of relationship, which would include reports and images." (Ex. J. Opp. Rowberg Dep. 106:4-107:3)

Following this uncertainty regarding the terms meaning, Dr. Rowberg conceded that there was nothing in the specification to support the proposition that related data means anything but images:

> Q. Is there anything in the specification that teaches that "related data" can mean anything other than images? And if there is, please find it.
> A. I don't know of a citation that teaches that.
> Q. And you are more than welcome to look. You're confident you won't find anything?
> A. I believe I tried this morning and couldn't find that." (Ex. J – Opp., Rowberg Dep. 109:13-21)

[1] DC Brief refers to DatCard's Brief; DC Exhibits refers to DatCard's Exhibits.

And finally to be successful on it's infringement claims relating to the '157 Patent it argues that a singular term is plural and "specific" doesn't necessarily mean specific.

DatCard needs a clean sweep on its construction of all the proposed terms. If not, the Court should find that the MediaWriter does not infringe the cited claims.

II. DESCRIPTION OF THE MEDIA WRITER

PacsGear's MediaWriter is a PACS accessory called a medical disk publishing device. It consists of a computer with a single monitor, a CD/DVD burning device and software which enables a user to select medical image studies[2] from a hospital's DICOM-conforming PACS image database and burn them onto a CD along with viewing software so they can be read by any computer. The MediaWriter workstation does not have a database which stores images and a user cannot search the MediaWriter's hard drive for image studies. The dialog box below shows how a user can select specific studies from a PACS archive:

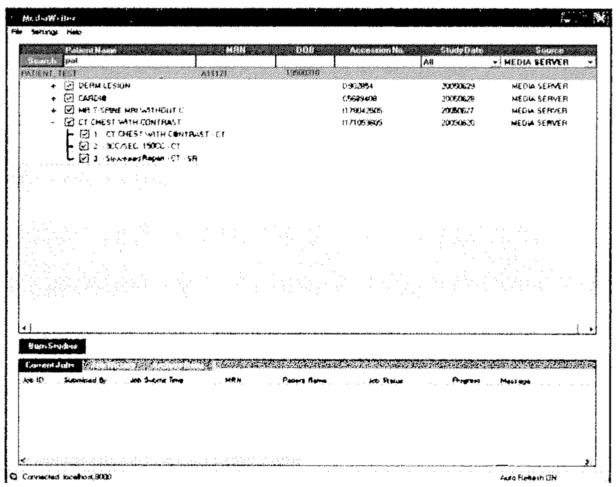


FIGURE 1

The MediaWriter does not conduct a automatic search for images related to the selected images. In other words, the only *images* that can be burned on to the CD are those

[2] A "study" is the term of art for the image or images taken by a modality in a single exam, whether it be one image (X-Ray) or hundreds (heart catheterization procedure). "Reports" are text data, such as diagnostic reports.

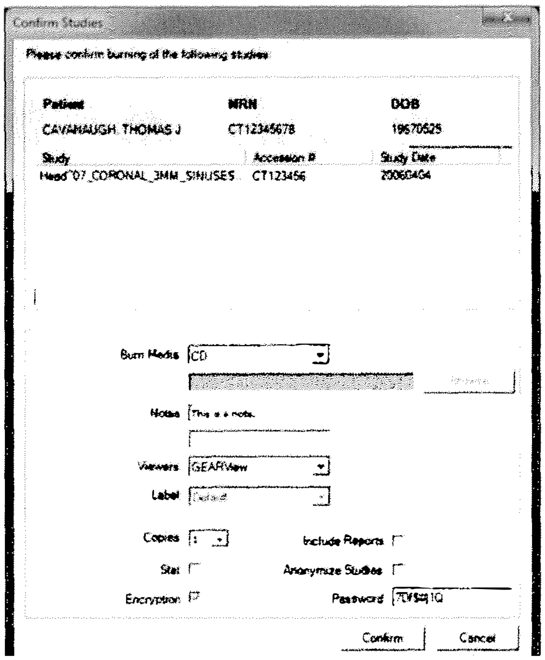
that are expressly selected by the user, originating in a PACS archive, using the dialog box as shown.

Starting with MediaWriter version 3.0, PacsGear added a feature to the software that allows the user to burn the radiologist's text reports interpreting the selected images onto the CD along with the selected images. ("Configure Reports Option", Ex. 217, User's Manual, p. 24-25).

The user of the MediaWriter and/or PacsGear, based on the customer's request, must specifically configure the MediaWriter software to search for these text reports, namely reports received by the MediaWriter via an HL7[3] feed or from a DICOM compliant archive, namely a PACS broker. This feature, however, does not allow the user to conduct a search for image studies. See Ex. 258, Cavanaugh Dec., ¶¶2-17. These reports can be stored in a distinct folder on the hard drive of the MediaWriter or on a PACS broker, sometimes referred to as a MitraBroker, which is external to the MediaWriter and designed to store text reports. These reports are in text format and are not DICOM images.

Several steps are necessary for the MediaWriter to burn medical images onto a CD. First, the user inputs the patient's name and is shown a menu of studies. He/she then selects all the image studies he/she wants to burn by moving a cursor to a box preceding each entry of the listed studies and clicking the computer's mouse, and then positioning the cursor over the Burn Studies button and clicking the computer's mouse (i.e., hitting the Burn Studies button on the dialog box above). After clicking on the computer's mouse to hit the Burn Studies button, a Confirm Studies dialog box pops up (see below), which allows the user to make additional choices, including whether to include text reports.

[3] HL7 ("Health Level 7") is the communication protocol used by a hospital to distribute written information from its Radiological Information System (RIS). The HL7 protocol sends diagnostic reports from the RIS to devices configured to receive them.



If text reports are desired AND the system has been previously configured to obtain such text reports, the user can check the "Include Reports" box and then click on the "Confirm" button and the images originating from the (DICOM) image database and the text reports from a separate location are burned onto a CD along with a viewing program. The CDs are automatically labeled with identifying information drawn from the patient demographics and relevant studies. (Ex. 217, User's Manual, pp. 24-25).

III. THE MEDIA WRITER DOES NOT INFRINGE THE '174 PATENT

A. Claim 1 of the '174 Patent

Claim 1 (Ex. 265, '174 Patent) reads:

> A system comprising:
>
> [1] a medical image server configured to receive medical image data generated by one or more imaging modalities, the medical image data being formatted in a standard medical imaging format;
>
> [2] a database configured to store medical image data generated by the one or more imaging modalities;
>
> [3] a plurality of browsing terminals configured to receive a user selection that defines selected medical image data for a patient;
>
> [4] a search module configured to automatically search the database for related data based on the user selection; and
>
> [5] a production station that is configured to record all of the

> following onto a data storage medium: the selected medical image data for the patient, recorded in the standard medical imaging format, the related data, and a viewing program that is configured to allow viewing of medical image data that is recorded onto the data storage medium by a general purpose computer that is not specifically configured with medical imaging software for viewing of medical images formatted in the standard medical imaging format."

B. Meaning of Database in the '174 Patent

Claim terms are to be interpreted under a hierarchy of evidence starting with the claims, the specification and the file history, and if still ambiguous, per extrinsic evidence. *Markman v Westview Instruments, Inc.*, 52 F.3d 979-980 (Fed. Cir. 1995) aff'd 517 U.S. 370 116 S. Ct. 1384 (1996). "Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Phillips v.AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005)

Dr. Horii concludes that database as used in the claims means "electronic collection of image data stored in a way to allow for easy search and retrieval following the request of a user". (Ex. B, Horii II, p. 6-7). His proposed definition is not plucked out of a dictionary, it is drawn from the context in which it is used in the claims. Dr. Horii's construction is supported not only by the claims but also by the specification and numerous outside sources: [4]

> A database is a collection of information that is organized so that it can easily be accessed, managed, and updated. In one view, databases can be classified according to types of content: bibliographic, full-text, numeric, and images. www.techtarget.com/definition (Ex. 269).

[4] 1) A database is collection of information organized in such a way that a computer program can quickly select desired pieces of data. Webopedia.com (Ex. 270)
2) A database is an application that manages data and allows fast storage and retrieval of that data. About.com (Ex. 271)
3) A database is a usually large collection of data organized especially for rapid search and retrieval (as by a computer). Merriam-Webster Online dictionary (Ex. 279)

DatCard's proposed definition of database ("a structured set of data held in a computer") is solely based on extrinsic evidence, (namely, an Oxford English Dictionary definition) and essentially ignores the claim language and the specification (Even the online version of the Oxford English Dictionary ("OED"), includes a requirement that the database be "accessible" in various ways).[5] "Properly viewed, the "ordinary meaning" of a claim term is its meaning to the ordinary artisan after reading the entire patent. Yet heavy reliance on the dictionary divorced from the intrinsic evidence risks transforming the meaning of the claim term to the artisan into the meaning of the term in the abstract, out of its particular context, which is the specification." *Phillips v. AWH Corp.* 415 F.3d. 1301, 1321 (Fed Cir. 2005)

One need look no further than the claims to conclude that Dr. Horii's proposed construction is the correct one:

The second limitation of the '174 patent - the first limitation to use "database" - states:

[2] "a database configured to store medical image data generated by one or more imaging modalities"

The next time database appears in the claim is in the fourth limitation, which states:

[4]" a search module configured to automatically search the database for related data based on the selection of a user".

Based on the claim limitations alone we know that both limitations are referring to the same database and the database (i) stores image data [2] and (ii) is searchable based on the user's selection [4]. As a result, database as used in claim 1 necessarily means "an electronic collection of image data stored in a way to allow for easy search and retrieval following the request of the user."

[5] Database is a structured set of data held in a computer, especially one that is accessible in various ways: *a database covering nine million workers.* OED (Ex. 272). This is the same definition Rowberg spouted from memory during his deposition (Ex. J – Opp., p. 29:17-23) – apparently, DatCard must have discovered the broader 2002 definition more recently.

The '174 specification supports Dr. Horii's proposed definition. For example, the databases identified in the specification as storing images, only store images. (e.g., Ex. 265, See Fig. 1 - "Image Server Database). Additionally, the inventor, Ken Wright testified at the time of the invention that the PACS database only stored images – it did not store text reports. (Ex. I – Opp., Wright Dep., pp. 148-149).

DatCard attempts to shift the focus by referring to the "production history database" as a database which stores text, is a red herring. The production history database stores data relating to the audit records. (Ex. 265, '174 Patent, 6:53-59). Although the production history database is one of many databases on the workstation's hard drive shown in the patent, the specification does not state or in any way imply that the production history database stores images.

DatCard also attempts to use the production history database as an example of a non-searchable database: "the specification **never** states that the database is searchable for audit records" (emphasis in original). (DC Brief p.6). It is difficult to conceive how DatCard can make the argument, that an "audit record" database is not searchable. The fact it stores production history information for audit purposes confirms that it is searchable. Otherwise how would one conduct an audit? DatCard's proposed claim language should therefore be rejected as the claim, specification and relevant dictionary definitions are quite consistent with Dr. Horii's proposed definition.

C. The MediaWriter Does Not Satisfy the Database Limitations

1. The MediaWriter

The MediaWriter searches the PACS for images and if the user selects some for burning on to a CD they are sent directly from the PACS to the CD burner through the MediaWriter. The MediaWriter acts as a buffer for the image data to increase the efficiency of the CD recording process. The MediaWriter does not have an image database. DatCard concedes as much when instead of using the term "database" it states that the MediaWriter "holds or stores **(buffers)** medical image data retrieved from the

PACS". (emphasis added) (DC Brief pp. 5-6). This buffer location is not a database and is not searchable:

Dr. Rowberg: "That really isn't searching. That's just receiving them. It knows where they are, it doesn't have to search for them..." (Ex. J - Opp. Rowberg Dep. 74:12-75:12) (See also, Ex. B, Horii II, p. 11; Ex. 217; User's Manual 4.0).

The '174 Patent describes a buffer system (like the one used by the MediaWriter) and not only doesn't identify it as a database but because it is just a buffer states that the images are not even "stored" through this process:

"In another embodiment, the application server 110 transmits data it received to the production stations 300A, 300B or 300C, without ***storing*** a copy of the data in the application server database." (emphasis added) (Ex. 265, Col 6:12-15).

Accordingly, the MediaWriter's buffer is not a "database".

2. Claim 1 Does not Read On the MediaWriter

MediaWriter does not satisfy limitations [2] and [4] of Claim 1 of the '174 Patent. As discussed above, claim 1 requires that the claimed database (1) store images [lim. 2], and (2) be automatically searchable for related image data at the request of a user, via a search module [lim. 4].

As discussed above, DatCard identifies the hard drive location which "holds or stores **(buffers)** medical image data retrieved from the PACS" as the "database" which satisfies the second limitation (Brief, p. 7), and the folder which stores text reports as the "database" which satisfies the fourth limitation (Brief, p., 14). This combination cannot satisfy the claim limitations for several reasons:

(1) A "buffer" is not a database[2]; a "buffer" is merely a location on the hard drive, which is temporarily used to increase the efficiency of a system.[6] The data buffer is not searchable and as the '174 patent doesn't even consider this type of data to be "stored" on the hard drive – because it merely passes through the workstation – a buffer can't be a

[6] A data buffer is a temporary storage area, which acts as a holding area before transferring it to a device. See Ex. 273 - for definitions of buffer.

database. (See above discussion and quote from the '174 Patent). Accordingly, the MediaWriter's buffer location cannot satisfy the database limitations.

(2) Limitation [4] requires the "database" to be searched. The MediaWriter cannot search its hard drive for images. The images merely pass through the MediaWriter on their way to the CD burner database. (Ex. B, Horii II, p. 11; Ex. 217, User's Manual 4.0). (Rowberg Dep., p. 74:12-75:12))

(3) The HL7 and other reports are stored in a "file system", which does not store images and is not a "database"[7], and even if it is, it is not the same "database" as the buffer location discussed above. In this case, "the database" in limitation [4] refers to the same "database" in limitation [2].[8]

Dr. Rowberg also confirms that the buffer location on the hard drive is not the same "database" as the folder storing HL7 reports.

> "Q. Based on your understanding, then, the two databases that are on the outside of the MediaWriter, the second PACS and the Mitra broker, and then the HL7 report database is on the local hard drive, correct?
> A. I believe so.
> Q. Okay. And then the fourth separate database is the local hard drive where the images are stored.
> A. That's the fourth database, yes." (Rowberg Dep., p. 172:2-11)

(4) DatCard also appears to contend that the "local drive" is the "database" which satisfies the above limitations. We presume it is referring to the MediaWriter's workstation's hard drive. A hard drive is not a database.[9] The OED defines a *hard drive*

[7] Dr. Rowberg opines on the difference between a database and file system: "A file system is handled by the operating system and stores files, obviously. It does not have the structure that a database has. For instance, the files might be totally different from each and not be a repeat of the previous file. In a database, the successive records are in some way structured and a repeat of the previous data set." (Ex. J – Opp., Rowberg Dep. 32:2-8).

[8] "Because it has defined "database" and then says "the database," I think it's referring back to the same one. So I would think it would be the same." (Ex. J -Opp., Rowberg Dep. 40:1-15).

[9] DatCard's reliance on PacsGear's inartful internal software spec requirements is extrinsic evidence and has no bearing on claim construction/related analysis.

as "a disc drive used to read from and write to a hard disk" and a *hard disk* as "a rigid non-removable magnetic disk with a large data storage capacity" (Ex. 274). In other words, one skilled in the art would not consider a hard drive a "database". A hard drive can store multiple distinct databases. The embodiment shown in Figure 1 of the '174 patent, for example, shows that the workstation can store several databases, all of which are distinct and separate databases in the same way Dr. Rowberg identified the four separate databases above. As the folder storing the HL7 reports is its own file system and does not store any of the same data as the image buffer location discussed above, such combination cannot satisfy the limitations [2] and [4] of Claim 1.

For all the above reasons, the MediaWriter does not infringe Claim 1 of the '174 Patent.

D. The MediaWriter Does Not Satisfy the Browsing Terminals Limitation

The third limitation of Claim 1 is:

> [3] a plurality of browsing terminals configured to receive a user selection that defines selected medical image data for a patient;

DatCard is correct that a browsing terminal is simply a computer terminal and that many facilities utilize multiple terminals in connection with their PACS. DatCard also agrees that the MediaWriter is a single terminal and therefore relies on contributory infringement for liability purposes. (DC Brief pp. 7-8). In order to establish contributory infringement DatCard must show that (i) there is direct infringement, (ii) Pacsgear had knowledge of the patent, (iii) the component has no substantial non-infringing uses and (iv) the component is a material part of the invention. *Fujitsu Ltd. v. NetGear Inc.*, 620 F.3d 1321, 1326 (Fed. Cir. 2010).

DatCard focuses on the MediaWriter's "Web Client" feature to satisfy the third limitation of the claim. The Web Client feature allows medical facilities to connect the MediaWriter from other workstations. Without agreeing that DatCard has satisfied the first two contributory infringement factors, it is quite clear that DatCard's infringement

allegations fall short because the MediaWriter, without the Web Client, has substantial non-infringing uses.

Pacsgear sold the MediaWriter for several years without the Web Client feature as it wasn't included in the early versions. (DC Ex. 2, Cavanaugh Dep., pp. 119:14-23). The MediaWriter's user's manual does not provide instructions on how to set up the Web Client feature (Ex. 217). That information is only provided if the customer specifically seeks to add the Web Client feature. (DC Ex. 13). In fact, many of Pacsgear's customers don't use the Web Client feature. (See e.g., California Pacific Medical Center, Loyola Hospital of Chicago and Mercy Hospital in Redding, California - Ex. 275).

Without the Web Client feature, the MediaWriter still searches for and receives image studies and burns them onto CDs, which is clearly a substantial non-infringing use.[10]. If nothing else, there is a question of fact whether the MediaWriter without Web Client constitutes "a substantial non-infringing use."[11] *C.R. Bard, Inc. v. Advanced Cardiovascular Systems, Inc.*, 911 F.2d 670, 674-675 (Fed. Cir. 1990)(District court's grant of summary judgment for plaintiff reversed where fact issues remained regarding whether the accused device was suitable for substantial non-infringing use.) Additionally, the fourth contributory infringement factor is not satisfied as a plurality of browsing terminals is not a material part of the invention. There is no functional difference between one, two, or a dozen browsing terminals.

E. The MediaWriter Does Not Automatically Search for Related Data

1. Proper Construction of "Automatically"

A dictionary definition of the word "automatically" is "acting or operating in a manner essentially independent of external influence or control;" and "without volition."

[10] DatCard relies on cases where the alleged infringing component at issue is a portion of software, where as the alleged infringing component here is the entire MediaWriter. (See e.g., *i4iL.P. v. Microsoft Corp.*, 598 F.3d 831 (Fed. Cir. 2010) (date picking component of Outlook software).

[11] Even though there might be a question of fact on this issue, the Media Writer still does not infringe the '174 patent, as Pacsgear has shown that it does not infringe several other limitations and therefore does not infringe Claim 1 of the '174 Patent.

(Ex. 276). This is essentially consistent with the context in which the term appears in the specification "without prompting for user selection" (Ex. 265, col. 7, ll. 53-55) and "without asking for user direction" (Ex. 265, col. 8, ll. 48-49). DatCard on the other hand contends that automatically means that "once initiated, the function is performed by a machine without the need for manually performing the function."[12] (DC Brief, p. 12) In essence, DatCard contends that as long as the machine selects images and burns them onto the CD, it doesn't matter if the user takes any other intervening steps. DatCard provides no support for this definition from the specification. (DC Brief pp. 11-13).

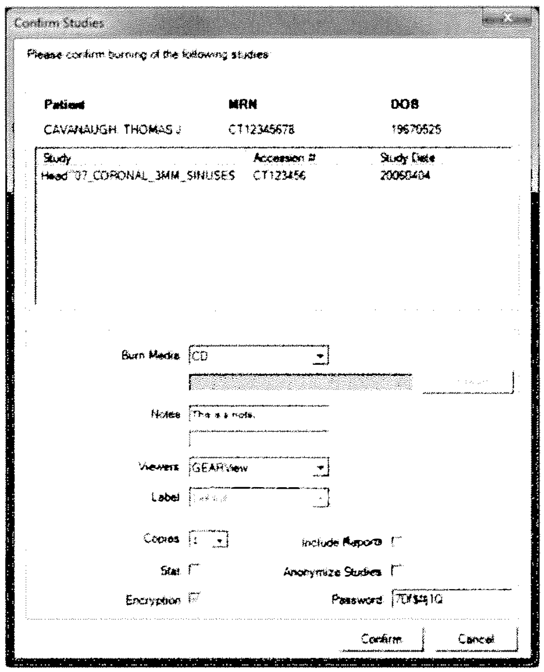
If DatCard's broad, unsupported definition was adopted, then many of the prior art references discussed in Pacsgear's invalidity motion, would anticipate the claim. For example, Heartlab's DICOMView system allows the user to search the a database once for selected images, and conduct another search for additional, related images for the same patient, and then send both the originally selected images and the subsequent related images to a CD recorder to be burned with viewing software - with some mouse clicks in between to accomplish it. (Petrocelli Dep. Ex. M – Opp. Pp. 35, 40-41, 50-51, 87-88, Ex. 202 DICOMView User's Manual, pp. 14 and 17-25, 36, 44-45). If, as DatCard suggests, "automatically" only means that the last step occurs without human intervention, then Heartlab and many other prior art references would anticipate this claim

2. The MediaWriter does not "Automatically" Search

At pp. 14 and 15 of its Brief, DatCard contends that MediaWriter satisfies the automatic search limitation [4] when it searches for reports utilizing the configured report option. This is untrue because the search does not happen automatically and requires significant user intervention. After the system receives the request for medical image data

[12] DatCard's reliance on the *College Net* case is not appropriate as the claims, specification and analysis are unique to that case and different in the present case. *CollegeNet, Inc. v. ApplyYourself, Inc.* 418 F.3d 1225, 1235 (Fed. Cir. 2005) (approved the claim construction only because it is "supported by the language of the claims, the specification and the prosecution history.")

related to a patient, the MediaWriter user must select image studies by positioning the cursor on a box next to each study and click the computer's mouse, then he must position the cursor over and click on the Burn Studies button at which point a Confirmed Burn dialog box will appear. Next the user can select whether or not it wants to include reports and make other changes only after it approves of the selections in the Confirm dialog box and clicks the "Confirm" button, will the images be burned onto the CD. (Ex. 217, pp. 10-13).



As this process requires significant user invention, it does not satisfy the fourth limitation, which requires a search for related data to occur automatically.

For all the above reasons, the MediaWriter does not infringe Claim 1 of the '174 Patent **even if** related data includes text reports.

F. The MediaWriter Does Not Automatically Search for Related Images

1. "Related Data" as used in the Claim Does Not Include Text Reports

DatCard contends that the fourth and fifth limitations' requirement for "related data" is satisfied by HL7 and MitraBroker text reports. (DC Brief p. 14). The term "related data" means image data and necessarily excludes these types of text reports.

In his report, Dr. Rowberg contended that HL7 and Mitra Broker text reports constituted both "related medical image data" and "related data." He was forced to concede he was wrong in his deposition where he confessed that related medical image data, medical data, and related data have no specific meaning to one skilled in the art: "it is out of my normal vocabulary." (Ex. J - Opp. , Rowberg Dep. p. 65). Turning to the specification for guidance, Dr. Rowberg also conceded that there was no reference in the specification to HL7 or Mitra text reports. (Rowberg Dep., p. 55). Dr. Rowberg confirmed that "related data" had no clearly defined meaning in the medical community (Rowberg p. 106:4 – 107:3). He also admitted that there was nothing in the specification to support the proposition that "related data" means anything but images Id. 109:13-21 and that related image data only refers to DICOM images. *Id.* at 69:3-7.

The best DatCard can do in terms of finding something in the specification that it contends refers to text reports, is the single sentence that says "One embodiment of the claim system allows for searching medical exam data that are related and placing such data on the same CD." (DC Brief p. 14; Ex. 265 p, 2:8-10).

The word "exam data" occurs a few times in the specification (not in the claims) but each time it is used synonymously with image data. For example, in connection with Figure 5, the specification states: "The user is prompted to select a patient in step 176 and selects exams of the selected patient in step 178." DatCard does not dispute and Rowberg admits that the selected data in the claims are always images. (Ex. J -Opp., Rowberg 56:7-16). The specification continues: "The user is then asked in step 180 if he/she desires to

find related data of that patient for comparative study." (Ex.265, col. 8:17-43). Not only does "comparative study" mean a related image study, but Figure 5 confirms that the related data in step 180, 182 and 184 is "Related Image Data."

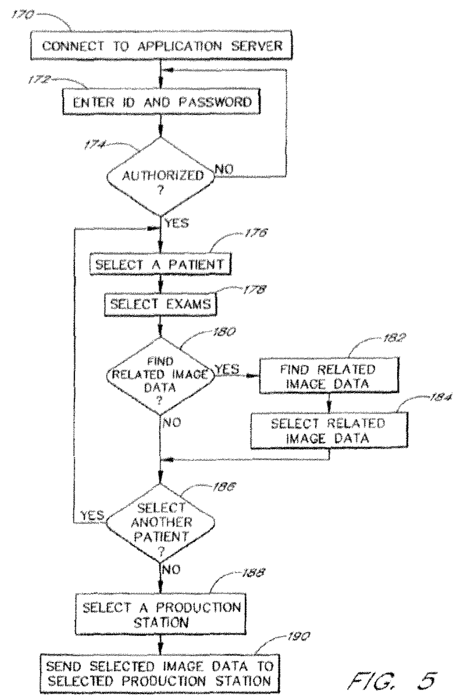


FIG. 5

There is nothing in the specification that would give one skilled in the art any suggestion that the system was designed to search for and burn text reports. As HL7 reports and other reports are generated by different sources and retrieved from different sources than DICOM images, if related data included text reports then the patent would fail the enablement requirement. *Boston Sci. Corp. v. Johnson & Johnson,* 647 F.3d 1353 (Fed. Cir. 2011), rehearing denied, rehearing *en banc* denied, 1011 U.S. App. LEXIS 21144 (Fed. Cir., Sept. 15, 2011)(Summary judgment for declaratory judgment of invalidity upheld where patents lacked adequate written description.)

Finally, the prosecution history confirms that the scope of the invention is limited to selected images and related images. In a declaration filed by the inventor, Ken Wright, during the prosecution of the '164 Patent – he declared under oath:

> *"The application server allows users to select medical images of interest and search for additional medical images that are related to the selected images. The selected and related medical images can then be recorded onto a portable data storage medium, such as a compact disc, using the standard medical imaging format."*

Declaration of Inventor, Ken Wright – Ex. 5, ¶3. No mention of text reports.

In light of the above, the term "related data" as with "related medical image data" and "medical data" all mean image data and do not include text reports (e.g., HL7, MitraBroker, etc.).

2. The MediaWriter Does Not Satisfy the Fourth Limitation of Claim 1

The database in the second limitation is configured to store medical image data and the fourth limitation requires a search module to search this database for related medical images. DatCard contends that the fourth limitation is satisfied by a search for text reports on folders stored on the workstations hard drive. (DC Brief p. 14). As related data does not include text reports, this limitation is not satisfied. Moreover, as discussed above, the file system used by the MediaWriter to store text reports is separate and distinct from the location on the hard drive, which acts as a buffer for images on their way to being burned.

For all the above reasons, Pacsgear does not infringe claim 1 of the '174 Patent.

As the MediaWriter does not infringe claim 1 it cannot infringe any of the claims dependent from Claim 1, namely claims 2, 3, 4 and 7 as identified by DatCard.

IV. DATCARD HAS NOT MET ITS BURDEN THAT PACSGEAR DIRECTLY INFRINGES CLAIM 7 AND 12 OF THE '157 HIPAA PATENT.

A. Claim 7 of the '157 Patent (Ex. 264):

> "7. A system for generating a portable computer-readable medium containing medical data for a first patient, wherein the medical data for the first patient are audited based on a plurality of audit records stored in an audit database, comprising:
>
> [1] a computer-implemented interface configured to receive two or more requests for production of stored medical data related to the first patient; and
>
> [2] an image production module that is configured, for each request for production of stored medical data related to the first patient;

> to produce the portable computer-readable medium containing the requested medical data related to the first patient, wherein the requested medical data comprises medical image data formatted in a standard medical imaging format used by a computer configured for viewing the medical image data; and
>
> [3] upon producing the computer-readable medium, to automatically transmit, to the audit database, audit data that is specific to the computer-readable medium produced in response to the request for stored medical data, wherein the audit data comprises at least an identification specific to the computer-readable medium, an identification of a requester of the stored medical data, and an identification of the first patient, and is for at least one audit record in the plurality of audit records in the audit database.

B. No Evidence of Two or More Requests for Production

The first limitation of claim 7 requires a computer implemented interface configured to receive two or more requests for production of stored medical data related to the first patient, the first limitation is then combined with the second limitation which requires the requested medical data related to the first patient (resulting from the two or more requests) to be burned onto a CD.

In DatCard's infringement analysis, it claims these limitations are satisfied by the user interface which allows the user to select multiple patient studies containing medical images and reports that are displayed in a "burn configuration dialog box." (DC Brief, p. 19 - citing to the MediaWriter User Manual, Ex. 3, pg. 06767). DatCard's infringement theory is that the first limitation is satisfied by a <u>single</u> request for production of multiple studies, relating to a patient - not two requests for production relating to the same patient, as required by the claim. As DatCard's infringement theory is based on a user making a single request for multiple studies and the claim requires the user to make two separate requests, DatCard's proposed bases for infringement fails.

C. The MediaWriter's Job Id. Number Doesn't Satisfy the Third Limitation

The last limitation [3] requires that upon producing the computer readable medium the system automatically transmit to the audit database, audit data that is specific to a computer readable medium produced in response to the request for stored medical data, wherein the audit data comprises <u>at least an identification specific to the computer readable</u>

medium and an identification of a requestor the stored medical data and an identification of the first patient.... The terms in dispute are "audit data that is specific to the computer readable medium."

1. Claim Construction

In order to demonstrate infringement, DatCard contends that the term "computer readable medium" is plural. (DC Brief, p. 22) Pacsgear believes that the plain and ordinary meaning of computer readable medium is that it refers to a single storage device (i.e, one CD). DatCard did not provide an OED definition of "medium" to support its construction this time, but we do. The OED states that medium is singular and more than one would be "media" or "mediums". (Ex. 277). As a result, the audit data must have an identification specific to each CD (singular).

The next claim construction issue concerns the term "specific". DatCard again refers to the OED, which actually has several definitions for "specific," one being "clearly defined or identified." The same Dictionary also offers another meaning: "belonging or relating uniquely to." (Ex. 278)

Turning to the specification for some clarification. The specification clearly refers to an identification number unique to a single CD.

The entry in the specification relating to the audit log is as follows:

> For each CD to be produced, the application server 110 adds one audit record to the production history database in step 144. The new audit record comprises the identification number of the CD and other relevant information about the CD such as the physician who requested the production (if any), the names of the patients whose exam images are on that CD. (emphasis added)

That's it! It only refers to CD in the singular and it talks about the "identification number of the CD" –again in the singular. In an attempt to show that a singular term can be plural, DatCard points to a different section of the specification which states that more than one CD with the same images can be made based on the "number of copies" value. (Col. 6: 23-28).

DatCard then makes the leap to "if the system required that each copy of the CD have a 'unique' identification number as Pacsgear contends, the value of the number of copies would not be needed." (DC Brief, p. 22). It is not clear what DatCard's point is here. That referenced sentence has nothing to do with the audit log (which only appears later in the specification), and merely allows the user to create duplicate CDs featuring the same images, much like a laser printer allows you to print multiple copies of the same document.

The appropriate construction of "identification specific to the computer readable medium" is "an identification unique to the single compact disc or other storage medium" onto which images resulting from the two requests for images for the first patient are recorded. DatCard's proposed definition of "an identification such as a clearly defined or identified number" of the computer readable medium (plural) is not supported by the claim language or the specification.

2. The MediaWriter's Job Identification Number Does Not Infringe

There does not seem to be a dispute regarding the way the MediaWriter works in connection with its audit log. Historically, the MediaWriter used both a disc ID to identify each individual disc and a Job ID to identify the entire job requested by the user.[13] Starting with MediaWriter version 4.0.1, PacsGear eliminated the Disc ID and only the Job ID remains. When the MediaWriter operator sends a series of image studies to the CD burner, the entire job, often consisting of multiple CDs, will be assigned a number in the audit log – therefore each individual CD will not have a specific identification number. As DatCard concedes, the MediaWriter's Job ID entry does not include identification that is unique to a single CD, hence its desire for a broader "plural" claim construction. As a result, MediaWriter's sold with only the Job ID number (post version 4.0) are outside the scope of properly construed claim 7.

[13] Pacsgear does not dispute that the disc ID satisfies the appropriate construction of this limitation.

As the MediaWriter does not infringe claim 7 of the '157 Patent, it does not infringe any claims dependent on claim 7, including claim 12.

CONCLUSION

DatCard needs to contort the claim language in order to get it to read on the MediaWriter. A reasonably construction of the claim terms, based on the intrinsic evidence, demonstrates that the MediaWriter cannot infringe the asserted claims.

Respectfully submitted,

Dated: January 23, 2012

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EXPERT REPORT OF STEVEN HORII, M.D.

In the Matter of DatCard Systems, Inc. v. PacsGear, Inc.

United States District Court For The Central District Of California

Case No.: SACV10-1288 DOC (VBKx)

[OUTSIDE COUNSEL ONLY – PURSUANT TO PROTECTIVE ORDER]

ABSTRACT

I have been engaged by counsel for Defendant PACSGEAR to offer my opinions on the validity of plaintiff DatCard's patents in suit. These patents relate to the electronic transfer of medical images and recording the images onto CDs.

The patents discuss Picture Archiving and Communications Systems, commonly called PACS. PACS are systems used for the digital transmission and storage of medical images, e.g., MRI's, CT Scans, Ultrasound. PACS are the means by which images created by the device are transmitted to a database, where they can be accessed by treating physicians' workstations and copied for distribution to those who need them, such as patients and referring physicians. Typical PACS systems conform to what the patents refer to as "a standard medical imaging format." In practice, that format typically is the DICOM Standard. DICOM consists of a detailed and comprehensive set of protocols that have been adopted worldwide. I have devoted much of my career over the past three decades to the development of DICOM.

DatCard's patents claim a simple DICOM-conforming medical image storage, transfer and copy system. Nearly all its features were built into systems conforming to the DICOM Standard more than five years before the first patent was applied for. All of the features claimed were well known in the literature and in practice before DatCard's claimed inventions. For

III. HISTORICAL BACKGROUND

A. The Use Of Film And Film Libraries

For close to a century, radiologists used film to capture, view, transfer and store the images. As Dr. Harry Fischer (Fischer 1982) teaches, film libraries were established to provide films to the physicians and other personnel caring for patients. If patients were transferred to other facilities, or if they needed their films for a second opinion, film libraries also provided the films (or copies) to patients for their patient folders.

Because the film was the sole image record of the examination unless it was copied and due to privacy concerns, means were established that paralleled the functions in a literary library. Films had to be signed out and a record kept of the borrower, information about the images (e.g., date, content, modality), the hospital person facilitating/authorizing the check out and when they were taken. The filmless system was broadly modeled to digitally emulate the film-based filing system. Seshadri (1992) provides a more thorough discussion of making the transition from film jackets to digitally based systems. (**Exhibit 6B**).

The organization of film libraries included the creation of film jackets that held a number of folders. The jacket served as a master folder and had space on the outside to record what folders were included. The folders themselves were typically organized by the type of image or by imaging technique and would contain subfolders if the patient had more than one of that particular imaging study along with any diagnostic reports.

B. Early Filmless Image Transmission

Early digitized medical systems were designed for communication of radiological images (e.g. University of Pennsylvania system discussed in Seshadri et al article 1990) within hospitals, for the diagnosis and monitoring of a patient's condition. These Picture Archiving and

Communication Systems were the early versions of the modern day PACS. However, because such PACS were hospital-based, most physicians outside the hospital did not have electronic access to patient images. For this reason, an early method of distributing images from PACS to non-hospital doctors was to print the images directly from the modality or other storage device on film and deliver them for viewing on the traditional lightbox.

The progress and development of digital media came from the consumer electronics industry. Vinyl analog records were replaced by digital Compact Discs (CD). Makers of personal computers took advantage of the large storage capacity of CDs and began to advocate for using the recordable CD for storage and distribution of digital information. Other medical specialties that used imaging, particularly cardiology, also made the transition to digital imaging. Conventional cardiac x-ray imaging used 35mm motion picture (cine) film, so cardiology film libraries contained many canisters of such films.

Digital imaging provided an opportunity to replace such film with electronic storage, but the cardiologist still had a requirement to view the dynamic imaging that the cine film provided. While video recording was one solution, analog video playback did not handle changes in playback speed or direction well. A digital media based solution was very much desired by the cardiology community. Because systems were essentially created ad hoc at the hospital level with the assistance of large OEMs, like General Electric, Philips and Siemens, there was no uniformity between one modality and/or PACS system and another, so the benefits of universal filmless transmittal of images could not then be realized.

C. The DICOM Standard

1. DICOM standardizes communication protocol between devices

In 1983, the American College of Radiology and National Electrical Manufacturers Association (ACR-NEMA) formed an interdisciplinary committee of radiologists, members from industry and computer engineering experts to develop a uniform protocol to enable completely filmless distribution of radiological images. That effort ultimately led to the DICOM standard.

The ACR-NEMA Committee was eventually re-named Digital Imaging and Communications in Medicine (DICOM) Standards Committee to reflect participation of additional groups including non-radiology medical specialists (e.g., cardiology) and foreign professional medical societies and standards bodies.

It was a given that the standard would enable transmission, viewing, searching for and storing of images from the full gamut of image modalities throughout the networked facility. The primary images and related images, such as previous studies, would have to be readily accessible to physicians, without detrimental changes to the workflow of healthcare providers. The objective was and is a "plug and play" system.

Any DICOM-based PACS typically is composed at least of equipment that receives the DICOM images from the equipment that images patients, stores the images and maintains a database so the images can be retrieved, and workstations that display the DICOM images so that radiologists and other healthcare providers can interpret or view them. The DICOM Standard provides infrastructure so that these components can operate irrespective of the imaging equipment manufacturer, so long as the imaging equipment conforms to DICOM. While all the Parts of DICOM are necessary for a digital healthcare enterprise, the core parts needed are Part 3 (PS 3.3) which defines the way images and related information are formatted, Part 4 (PS 3.4)

which specifies the various services that are necessary to store, move, find, and retrieve the images and associated information. Other parts define the particulars of communicating DICOM images over computer networks (Parts 5, 7, and 8 (PS 3.5, PS 3.7, PS 3.8)).

Updates of DICOM are issued yearly. The Standard now consists of some 18 parts of detailed specifications. To make it easier to select and install DICOM-compliant systems, the Standard includes a part on Conformance. This part requires any manufacturers claiming conformance to DICOM to describe that conformance in a specific, standard manner.

The DICOM committee chose to enable the flow of digital information so as to replicate the pre-digital, film-based system. DICOM implementers recognized that portable media, such as CD's and DVD' were analogous to film-jackets and that inserting a CD into a computer is the equivalent of putting an x-ray onto a lightbox. This model was deliberately adopted to mimic familiar behavior of medical personnel in the pre-digital world.

2. CD selected for the storage and exchange of DICOM images

Before DICOM, the most widely used digital medium was magnetic tape. I was chair of the Working Group that developed a standard applicable to magnetic tape, which ACR-NEMA published in 1991. Shortly thereafter, the burgeoning use of CDs for data recording and the desire by cardiology for a cine film replacement, led to our group being tasked to generate standards for other media. The first medium for which we developed a standard was recordable CD (CD-R). This of course led to the CD being selected as a portable storage medium of choice, as spelled in the DICOM Standard, specifically Part 10.

As Dr. John Elion teaches in DICOM Media Interchange Standards for Cardiology: Initial Interoperability Demonstration (Elion 1995):

> "Selection of the exchange medium was a challenging task and a large variety of digital storage technologies were considered. After lengthy discussion and debate, the

> recordable 5.25 inch [sic] optical compact disk (CD-R) was selected. The storage format on the CD-R is based on international standards, among them ISO 9660. The medium is similar to the CD-ROM used in popular multimedia applications."

After publication of the DICOM Standard for CD-R, the American College of Cardiology (ACC) elected to implement the standard and demonstrate it at their scientific meeting. Software to create the discs and display the contents was written by Brown University under contract with the ACC and a CD containing a set of DICOM images was created and replicated. The ACC called the discs "Digital Interchange Standards for Cardiology (DISC)". At the 1995 ACC meeting, thousands of these discs were distributed and attendees could take them to a number of participating vendors where the contents could be viewed (Elion 1995).

The next year the ACC again took the opportunity at their annual meeting to demonstrate the benefits of the DICOM standard. This 1996 version of the DISC contained various DICOM medical images from a number of studies including angiograms, ultrasound images and several nuclear studies. In that year the ACC group headed by Dr. Steven Nissen also included a public domain DICOM viewer on the CD, which enabled the recipients to review the images on any Windows based personal computer. [Nissen, Steven "Evolution of the Filmless Cardiac Angiography Suite" -- Am. J. Cardiology, August 1996, Exhibit 77, Deposition of Jack Cusma.] At approximately the same time the European Society of Cardiology created a similar CD for distribution at their Annual Meeting in Birmingham, England, which included numerous DICOM studies on a fictitious Jon Doe along with viewing software, which enabled viewing on any personal computer. [Ratib Declaration; DISC '96 Birmingham Documents.]

D. Proliferation Of DICOM Conforming Systems—1996 Forward

The issuance of the first DICOM Standard in 1993 jump-started the progress of digitizing the medical community worldwide. One of its main contributions is that the equipment

manufactured by a wide-array of companies, including imaging devices (MRI, CT, etc.), PACS themselves, CD readers/writers, workstations and storage systems all essentially speak the same language. This makes it possible to interconnect equipment from various vendors to suit particular medical imaging needs. Some of this equipment included products that coupled the DICOM query, retrieve or send functions with the Standard's selection of the CD as the preferred DICOM storage device – some of which are discussed below. The fact that the patents involved in this case list over 700 prior art references reflects the explosion of PACS related technology ushered in by DICOM.

IV. CLAIM CONSTRUCTION AND VALIDITY OF THE '164 PATENT

A. Person Of Ordinary Skill In The Art

In connection with the interpretation of the patents, I understand I am to adopt the viewpoint of a hypothetical person of ordinary skill in the art. Counsel has instructed me on the factors that courts have followed in profiling such a person include the educational level of the inventor; type of problems encountered in the art; prior art solutions to these problems; rapidity with which innovations are made; sophistication of the technology; and the educational level of active workers in the field.

The art here is the design of systems implementing the electronic transfer and copying of DICOM medical images. A person of ordinary skill would need a strong background in the architecture of information systems, and thorough familiarity with DICOM. That person would also have to understand the demands of the medical environment, e.g., confidentiality of patient information and the needs of treating and referring physicians for prompt and easy access to a wide variety of patient images and information.

computers not specifically configured with standard medical imaging software for viewing of medical images."

The first element calls for a server that receives digital medical image data from at least two imaging machines ("modalities"), the data formatted according to DICOM (or some other "standard medical imaging format"). As discussed above, Parts 3 through 8 of the DICOM Standard specifically teach the methodology necessary for modalities to communicate with networked devices, including sending DICOM images to servers on a PACS device, a workstation or a CD burner. Nothing requires interpretation, except perhaps the meaning of "specialized computers," which appears to be later defined in the claim as one "specifically configured with standard medical imaging software for viewing of medical images." I interpret "specialized computers" to mean computers containing DICOM viewing software.

The second element is the database for storing digitized medical image data. The person of ordinary skill would readily understand this limitation.

The third element calls for more than one browsing terminal, whether a computer networked to the database which stores the DICOM medical images, the terminal is capable of receiving the user's [e.g. the physician's] selection of the medical image data such as the patient's most recent MRI. The meaning of the element appears unambiguous.

The fourth element is a "search module" that searches the database for "related medical image data." "Related medical image data" is not a standard term in my field, but I believe its meaning is unambiguous from the specification. In my opinion, the term "related medical image data" means digital medical images, to the exclusion of written materials, such as diagnostic reports. This would be clear to the person of ordinary skill from the specification at column 2, ll.

information on their patients, and labeling CD's is a better idea than putting unlabeled CD's in a computer to find out to whom they pertain. Whether to generate labels when image data is loaded on CD's using a Rimage unit or to hand-write the filing information on a the blank label of a CD is simply a design choice.

V. CLAIM CONSTRUCTION AND INVALIDITY OF THE LATER PATENTS

A. The '597 Patent

1. Construction Of Claims 1 And 6

The vocabulary of claim 1 of the '597 patent[5] (issued in 2010) is largely the same as in the '164 patent. Claim 1 introduces three new terms: (1) the term "automatically" in connection with searching and retrieving data, and (2) use in some limitations of the seemingly more general term "medical data" instead of "medical imaging data," in describing what is searched for and retrieved and (3) searching two databases.

"Automatically" and "medical data" are neither specifically defined in the claims, nor do they have a well-defined meaning in the art.

[5] "1. A computer-implemented method for automatically generating a portable computer-readable medium containing medical data related to a patient, comprising:

[1]receiving, via computer-implemented interface a request for medical data related to the patient;

[2]automatically searching a first computer database via a first database interface for a first set of medical imaging data related to the patient based on the received request;

[3]automatically retrieving the first set of medical imaging data related to the patient;

[4]automatically searching, based on the received request, a second computer database via a second database interface for *additional medical data* also related to the patient, wherein the second interface is different from the first interface;

[5]automatically receiving the additional *related medical data;* and

[6]automatically generating a portable computer-readable medium, at a production station, containing the first set *of medical imaging data* related to the patient and the *additional related medical data,* wherein the first set of medical imaging data is formatted in a standard medical imaging format used by a computer configured for *viewing the medical imaging data.*

The specification at col. 4, l. 44 to col. 5, l. 19, discusses the option of setting a PACS so that when the user requests image data from a first database, that request will automatically trigger transmittal of related image data from a second database. That is, a user who requests image data on one database will receive image data from a second database, possibly an archive database that is related to what was actually requested.

We know from the image input devices (modalities) listed on the left side of the matrix in Figure 2 that the second database includes other ("related") medical *image* data. The claim also requires the image data on one database to be formatted in the standard format (DICOM), without placing any limitation on the formatting of the data in the second database. Again, we know that the second database may but is not required to store images in DICOM format.

The major problem with construing the second database to allow for copying of written data, such as medical diagnoses, is that the system disclosed in the specification describes the information to be recorded on CD as consisting of image data[6] and not diagnostic text reports or other non-image data. In addition to the input devices shown in the Figure 2 matrix, the image server (Figure 1, 200) shows inputs only from image-producing devices.[7] Figures 3 and 5 also refer (Figure 3; 122, 134, 143; Figure 5; 180, 182, 184, 190) to image data and related image data only.

Additionally, Mr. Wright testified that the eFilm Medical viewing software, which was copied onto CD's, ('164 Patent col. 4, ll. 33-34) only reads and displays images and cannot open

[6] Although it does not appear to be relevant here, DICOM does provide for some identifying text to be included in a Standard DICOM data set (as DICOM image plus "header" information) with certain elements to be necessarily defined to contain text (e.g., "patient name").

[7] Figure 1 shows an Image Scanner (500) which is described as an image producing device in the specification as it only teaches that it scans and transfers "medical image data stored on film".

The independent claims of the '174 Patent also use the term "related data" instead of "related medical image data". Although Claim 5 of the '174 Patent uses the tenn "related medical image data" interchangeably with "related data". For the reasons discussed above in connection with the '597 Patent, the specification suggests that Claim 5 is correct, in that related data does mean related medical image data.

2. The '174 Patent claims are anticipated and obvious

The claims here are quite similar to the claims in the '164 and '597 patents and are anticipated (Claims 1 and 8) or rendered obvious for the same reasons.

D. The '422 Patent

1. A different person of ordinary skill in the art

Unlike the other patents, the '422 Patent focuses on the inner workings of the underlying software program. All the claims relate to the inclusion of a "timer" to determine whether all the data has been received and is ready to copy onto a CD. The claims here also use the following new terms: timeout period, timestamp, timer and timeout interval, which are not well defined in the specification. Although the person of ordinary skill in the art I have posited would recognize the need for a timer, that person would not necessarily be sufficiently knowledgeable on the technical side of computer programming to fully understand the programming issues raised by the '422 patent. On the other hand, at the programming level, relatively little knowledge on the medical side is required to understand the lion's share of the '422 claims. I understand that PACSGEAR has retained a computer consultant, Mr. Jestice, to evaluate this patent, from the point of view of a person of ordinary skill in the field of "computer programming, database programming and storage devices." I agree with Mr. Jestice's assessment.

REBUTTAL EXPERT REPORT OF STEVEN HORII, M.D.

In the Matter of DatCard Systems, Inc. v. PacsGear, Inc.

United States District Court For The Central District Of California

Case No.: SACV10-1288 DOC (VBKx)

[OUTSIDE COUNSEL ONLY – PURSUANT TO PROTECTIVE ORDER]

I. SUBJECT MATTER

I have been engaged by counsel for Defendant PACSGEAR to review and comment on the expert report of Alan Rowberg, M.D., specifically as to the '164 Patent, the '597 Patent and the '174 Patent; although some of my comments may be applicable to other patents and related reports.

II. QUALIFICATIONS

I am Professor of Radiology at the University of Pennsylvania School of Medicine. My complete C.V. is attached as **Exhibit 1**.

I received my M.D. from the New York University School of Medicine in 1976. I became board-certified in diagnostic radiology in 1980 and joined the faculty at N.Y.U., where I earned the rank of Associate Professor with Tenure.

I left NYU in 1988 to become Clinical Director of the Image Management and Communications Section in the Radiology Department at Georgetown University. My principal responsibility was as a radiologist and information technology expert for the Digital Imaging Network Systems (DINS) project. This project was the proof-of-concept for filmless radiology in support of teleradiology and battlefield care and was funded by the United States Army Medical Research and Development Command. The project culminated in the testing of filmless

fourth elements of Claim 9 : Element 2 of the claim, as noted above, states, "a database configured to store medical image data generated by a plurality of modalties;" Element 4 of the claim further states that " a search module configured to search the database for related medical image data that is related to the selected medical image data;" A person of ordinary skill in the art would understand "database" here to mean the electronic collection of image data stored in way to allow for easy search and retrieval following the request of a user.

The third element calls for more than one browsing terminal, whether a computer networked to the database which stores the DICOM medical images, the terminal is capable of receiving the user's [e.g. the physician's] selection of the medical image data such as the patient's most recent MRI. The meaning of the element appears unambiguous.

The fourth element, as noted above, is a "search module" that searches the database for "related medical image data." "Related medical image data" is not a standard term in my field, but I believe its meaning is unambiguous from the specification. In my opinion, the term "related medical image data" means digital medical images, to the exclusion of written or electronic text materials, such as diagnostic reports. This would be clear to a person of ordinary skill and is reflected throughout the specification. For example, at column 2, ll. 38-52, three different categories of possible related medical image data are given, all consisting of images, and nothing else. Additionally, claim 9 of the '164 Patent states that related medical image data is recorded in the standard medical imaging format. This further requires that the "related medical image data" be DICOM medical images and not text reports. Additionally, at the end of column 4, the specification discusses "related medical image data storage units" (identified as PACS 1 and PACS 2), as the source of the related medical images.

V. CLAIM CONSTRUCTION AND NON-INFRINGEMENT OF THE LATER PATENTS

A. The '597 Patent

1. Construction Of Claims 1 And 6

The vocabulary of claim 1 of the '597 patent[4] (issued in 2010) is largely the same as in the '164 patent, however, Claim 1 introduces three new terms: (1) the term "automatically", (2) the use, in some limitations, of the seemingly more general term "medical data" instead of "medical image data," in describing what is searched for and retrieved and (3) searching two databases.

"Automatically" and "medical data" are neither specifically defined in the claims, nor do they have a well-defined meaning in the art.

The specification at col. 4, l. 44 to col. 5, l. 19, discusses the option of setting up the system so that when the user requests image data from a first database, that request will automatically trigger transmittal of related image data from a second database. That is, a user who requests image data on one database will automatically receive image data from a second

[4] "1. A computer-implemented method for automatically generating a portable computer-readable medium containing medical data related to a patient, comprising:

[1]receiving, via computer-implemented interface a request for medical data related to the patient;

[2]automatically searching a first computer database via a first database interface for a first set of medical imaging data related to the patient based on the received request;

[3]automatically retrieving the first set of medical imaging data related to the patient;

[4]automatically searching, based on the received request, a second computer database via a second database interface for *additional medical data* also related to the patient, wherein the second interface is different from the first interface;

[5]automatically receiving the additional *related medical data;* and

[6]automatically generating a portable computer-readable medium, at a production station, containing the first set *of medical imaging data* related to the patient and the *additional related medical data,* wherein the first set of medical imaging data is formatted in a standard medical imaging format used by a computer configured for *viewing the medical imaging data.*

database. The specification at Col. 8 ll. 46-49 states: "*In another embodiment, once the user has selected a patient/exam combination, the application server automatically searches for related data without asking for user direction.*"

We know from the image input devices (modalities) listed on the left side of the matrix in Figure 2 of the patent that the second database includes other ("related") medical *image* data. The claim also requires the image data on one database to be formatted in the standard format (DICOM), without placing any limitation on the formatting of the data in the second database. Again, we know that the second database may, but is not required to, store images in DICOM format.

The major problem with construing the second database to allow for copying of written data, such as medical diagnostic reports, is that the system disclosed in the specification describes the information to be recorded on CD as consisting of image data[5] and not diagnostic text reports or other non-image data. The patent fails to even mention Mtira broker or HL7 fed reports. In the year 2000, I am not aware of any PACS which stored reports and the DICOM PS3 standard for Structured Reports did not yet exist, so there were no DICOM Structured Reports. Reports were typically stored in the radiology information system (RIS). In addition to the input devices shown in the Figure 2 matrix, the image server (Figure 1, 200) shows inputs only from image-producing devices.[6] Figures 3 and 5 also refer (Figure 3; 122, 134, 143; Figure 5; 180, 182, 184, 190) to image data and related image data only.

[5] Although it does not appear to be relevant here, DICOM does provide for some identifying text to be included in a Standard DICOM data set (as DICOM image plus "header" information) with certain elements to be necessarily defined to contain text (e.g., "patient name").
[6] Figure 1 shows an Image Scanner (500) which is described as an image producing device in the specification as it only teaches that it scans and transfers "medical image data stored on film".

retrieving the first set of medical imaging data; searching, based on the received request, a second computer database via a second database interface for additional medical data also related to the patient;

receiving the additional related medical data;

and generating a CD at production station, containing the first set of medical imaging data and the additional medical data.

In other words, upon entry of a request for selecting a patient's medical image data, a CD is burned containing medical image data from one database and medical image data from a second database, without user intervention.

The MediaWriter doesn't work this way. After the user of the MediaWriter satisfies the first limitation by entering a *request for medical data related to a patient* (i.e., by entering a patient's name or other identifier) a CD with images from multiple databases is not automatically produced. Instead, the user will first need to select specific studies that he wants to copy or all studies relating to the patient. After that he will click the burn studies button. After that a confirmation panel will appear where he will have other options. For example, if he wants reports, he will have to ensure that the enable reports button is checked. See Figure 3.2 – User's Guide 4.0. After ensuring that the settings on the confirmation panel are correct, he will click the confirm button. After all the above steps are completed, the selected studies will then be downloaded and burned on to the media.

The MediaWriter also does not have a first or second database that are searchable for medical image data. A PACS is not part of the MediaWriter and the MediaWriter does not have the equivalent of the DatCard image server (Figure 1, 200). The MediaWriter can be configured to connect to a PACS but not all medical facilities or imaging centers have a PACS and Dr.

Rowberg has not provided any evidence to support his position that MediaWriters are connected to multiple PACS. Additionally, it appears that very few if any medical facilities are set up to collect, search for and burn Mitra broker or HL7 fed reports. (PACSGear's Supplemental Response to Interrogatory 11; Fossum Dep. p. 35; Loyola Medical CenterPG026192-26206), Mercy Hospital (PG026191).

Dr. Rowberg appears to contend at pg. 46 of his report that only customers using the MediaWriter in conjunction with a second PACS, second imaging modality, report broker or HL7 feed satisfy this element (i.e, automatically receiving the additional related medical data). Whether or not this happens is left up to the customer. Additionally, as discussed above, the text reports generated by the report broker and HL7 feed do not constitute medical image data. For all the above reasons the MediaWriter does not infringe Claim 1 of the '597 Patent.

Claim 6 is a claim with limitations very similar to Claim 1 – so much of the above analysis applies. The fourth limitation of Claim 6 requires that the application server be coupled to the first and second database, both of which are searchable. The MediaWriter does not have a first and second database that are searchable for medical image data. A PACS is not part of a MediaWriter. Dr. Rowberg contends that this element is satisfied by the MediaWriter's application server connected to a PACS and either a second PACS, a searchable database on the local hard drive and/or reports broker. Whether these secondary connections are made is entirely up to the customer and are not necessary for the operation of the MediaWriter. As shown by the testimony of Mr. Fossum and correspondence from Loyola Medical Center and Mercy Hospital, medical facilities can and do use the MediaWriter with a single PACS and without including reports. Additionally, as discussed above, these reports do not constitute medical image data.

The last limitation of the Claim 6 requires *"a production station configured to generate a portable computer-readable medium containing the* *__first set of medical imaging data__* *related to the patient and the* *__additional related medical image data__*, *wherein the medical imaging data is formatted in a standard medical imaging format used by a computer configured for viewing the medical imaging data."* In other words, this limitation requires that all the data burned on the CD be image data formatted in DICOM format. The broker generated reports and the reports generated by HL7 feeds are text reports, not formatted in a standard medical imaging format, and therefore do not satisfy this limitation.

C. The '174 PATENT

1. Claim Construction

The primary difference between the independent claims of the '174 Patent and independent claims of the '164 Patent is that the '174 Patent claims are a little broader (e.g., only require "one or more modalities" instead of a plurality) whereas the claims of the '164 Patent require a plurality of modalities and the element relating to the search of the database for related data happens "automatically." The independent claims of the '174 Patent also use the term "related data" instead of "related medical image data" as does the '164 Patent. Claim 5 of the '174 Patent, however, uses the term "related medical image data" interchangeably with "related data". For the reasons discussed above in connection with the previous patents and the specification, related data is synonymous with related medical image data.

2. The '174 Patent claims are not infringed by the MediaWriter

The claims here are quite similar to the claims in the '164 and '597 patents and are not infringed for similar reasons.

The second limitation of Claim 1 is a *database configured to store medical image data generated by one or more imaging modalities*. The two databases identified by Dr. Rowberg to satisfy this limitation are (i) the local hard drive which stores the medical images but is not searchable by the user and (ii) PACS/imaging modalities.

The third limitation of Claim 1 requires *a plurality of browsing terminals configured to receive a user selection that defines selected medical image data.* The MediaWriter includes only a single workstation. It is up to the medical facility to determine whether it wants to connect to more than one browsing terminal and many facilities choose not to. (e.g., California Pacific Medical Center, Loyola Medical Center and Mercy Hospital of Redding, CA).

The fourth limitation of Claim 1 requires *a search module configured to automatically search the database for related data based on the user selection.* Dr. Rowberg offers the following various theories on how this limitation is satisfied:

1) *The MediaWriter is capable of storing reports received from HL7 feeds or brokers on its hard drive.* The files which store these html reports on the MediaWriter's local drive do not contain medical images and are not the same "database" previously referenced in the first limitation of Claim 1 which stores medical images. The received medical images discussed in the first two limitations are not stored in this folder. Additionally, as discussed above, many facilities are not set-up on the network to receive reports and even those that are set-up on the network do not automatically search for the reports, as the "Include Reports" box must be checked.

2) Dr. Rowberg next contends that the "related data" includes DICOM Structured Reports or DICOM images, which are scanned into a PACS. As discussed above, these Structured Reports and/or scanned images are part of the "selected" studies, as they would be

burned on to the CD because they were "selected" by the user not because of a search module configured to search for image data related to the selected medical image data.

3) Dr. Rowberg also contends the MediaWriters are configured to search the database for related data "via a report broker, such as a Mitra broker." Again, this would not happen automatically as Dr. Rowberg concedes that the user must first check the "Includes Reports" box. Additionally, the Mitra brokers and other brokers are not part of the MediaWriter. They are also a separate and distinct database compared to the "database" Dr. Rowberg identified in connection with the first limitation of Claim 1. Dr. Rowberg opines that there are "insubstantial differences between searching the same database for related medical images data and searching another database for related medical image data." While technically-speaking searching multiple databases versus a single database could be accomplished by one skilled in the art, the scope of Claim 1 is specifically limited to searching a single database. In my opinion, a system which searches multiple databases versus a single database performs a substantially different function in a substantially different way to achieve a substantially different result.

The final limitation of Claim 1 requires a production station configured to record the selected and related medical image data onto a CD along with viewing software. As discussed above, the patent specification only discloses the searching for and burning of medical images onto a CD. Accordingly, where Claim 1 refers to "related data", it appears that proper construction of the term in view of the specification is "medical image data". As the text reports discussed above by Dr. Rowberg are not medical images, this limitation of Claim 1 is also not satisfied.

For all the above reasons, I do not believe that the MediaWriter infringes Claim 1 of the '174 Patent.

Claims 2-5 and 7 are based on Claim 1 and therefore do not infringe for the same reasons discussed above.

Claim 8 of the '174 Patent is quite similar to Claim 1.

The first and second limitations essentially require receiving DICOM medical images from one or more modalities and storing them in a database. At page 68, the only "database" Dr. Rowberg identifies is the "local hard drive (database) that stores the received medical image data." For the reasons discussed above, this is not a database.

The third limitation is "receiving a user selection that defines selected medical image data for a patient." At pages 68-69, Dr. Rowberg states that "A user can select some or, by default, all of the studies returned in response to a search.... After the user confirms the selection, the Accused Product is configured to execute a DICOM query/retrieve that queries the PACS (or other DICOM archive, such as an imaging modality) for medical image data matching the selected study or studies retrieves this medical image data from the DICOM archive. In this way, the user's selection defines the selected medical image data." As discussed above, a "plurality of browsing terminals" is not a typical configuration of the MediaWriter.

The fourth limitation is *automatically searching the database for related data based on the user selection.* The only "related data" identified by Dr. Rowberg are the reports created by HL7 feeds or Mitra broker reports, which Dr. Rowberg contends are stored on the local hard drive. These are not found on the same "database" identified in limitations 1 and 2 above. It is my understanding that the reporting feature is typically not enabled and when it is the reports are stored in a separate folder on the local hard drive. The received medical images discussed by Dr. Rowberg in connection with the first two limitations are not stored in this folder. For the reasons discussed above, searching one database is not the equivalent of searching two databases.

Additionally, the folder containing the report is not configured to be automatically searched, as the "Include Reports" box must first be checked. For the reasons discussed above, related data is synonymous with related medical image data, which further negates Dr. Rowberg's contention that reports constitute the related data that is burned on to the CD.

INDIRECT INFRINGMENT

Dr. Rowberg makes several statements throughout his report regarding indirect infringement, including contributory infringement and inducing infringement. It's my understanding that before you can have indirect infringement, you must have direct infringement. As discussed above, I have concluded that there is no direct infringement of the above claims, therefore there is no indirect infringement. At this point the Court has yet to construe the claims. If necessary, I will revisit this issue after the claims are construed.

NON-INFRINGING ALTERNATIVES

At the end of his Report, Dr. Rowberg makes a quick reference to products made by Sorna, Nautilus, Data Distributing and SST. He makes some sweeping statements regarding how some of the products infringe claims 9 and 15 of the '164 Patent and claims 1 and 8 of the '174 Patent. Claims 9 and 15 of the '164 Patent and claims 1 and 8 of the '174 Patent require, among other things, searching for selected and related medical image data, as those terms are defined, on the same database and a plurality of browsing terminals. Dr. Rowberg fails to provide a claim chart or a detailed explanation of how each limitation of the asserted claims is satisfied by the referenced product.

Some additional alternatives that Dr. Rowberg fails to discuss are the use of an existing CD-burning product to serve additional locations or demands of a medical facility. Similarly, a

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

\- - -

DATCARD SYSTEMS, INC., a California corporation,

Plaintiff,

vs.

PACSGEAR, INC., a California corporation,

Defendant.

Case No. SACV 10-1288 DOC (VBKx)

(Complete caption on next page.)

NON-CONFIDENTIAL PORTION

30(b)(6) DEPOSITION OF DATCARD SYSTEMS, INC.

BY AND THROUGH KENNETH LOUIS WRIGHT

LOS ANGELES, CALIFORNIA

THURSDAY, AUGUST 4, 2011

ATKINSON-BAKER, INC.
COURT REPORTERS
(800) 288-3376
www.depo.com

REPORTED BY: MARY FERGUSON, CSR NO. 8769

FILE NO.: A5073A3

EXHIBIT I - Opp.

of Claim 9? 15:15:35
A. Yes, I did. 15:15:36
Q. Now, is the medical image data -- you already did discuss that the medical image data that's been selected refers to images. 15:15:37 15:15:44 15:15:47
Is the medical image data that's related, is that also DICOM images? 15:15:51 15:15:55
A. No. As I testified before, related medical image data is data that's related to the medical image, but it could be anything. 15:15:59 15:15:59 15:16:05
Q. So in this claim, then, the term "medical image data," when initiated with the word "selected," refers to images only, but it means something else when "related" is in front of it? 15:16:19 15:16:26 15:16:32 15:16:35
A. I am not the author of this patent claim, but as I read this claim, not being a patent attorney, the way the claim is laid out in the sequence it's laid out, I believe that the selected medical image data refers to the study on the screen that is being selected by the user, relates to medical images, and the related medical image data is related data to the medical image that could be anything. 15:16:38 15:16:42 15:16:45 15:16:49 15:16:53 15:17:01 15:17:09 15:17:13 15:17:18
Q. PACS are designed to store the medical images, right? 15:17:36 15:17:43

A. That is correct. 15:17:43
Q. Are they designed to store any HL-7 reports or any text reports? 15:17:46 15:17:54
A. In what time frame? 15:17:55
Q. 1999/2000. 15:18:00
A. Most have not stored results; they just stored images only. So they did not store HL-7 back in '99. 15:18:02 15:18:06 15:18:13
Q. So back in '99, the PACS only stored images? 15:18:14 15:18:17
A. Images. 15:18:18
Q. DICOM images, I guess, to be to the point? 15:18:19
A. To be more accurate, correct. 15:18:24
Q. Was that the case -- when did that change? 15:18:32
A. I don't know when it changed. 15:18:37
Q. Did it change really soon after that or was it mid-2000s or just last year? 15:18:43 15:18:46
A. Probably five or six years ago. 15:18:56
Q. So 2005/2006 time frame? 15:19:07
A. Yeah, but it didn't change for all of them. It changed for a few. Many still don't store anything but images, probably 80 percent. 15:19:10 15:19:14 15:19:17
Q. Only store images? 15:19:20
A. Yeah, only store images, even today. 15:19:21
Q. If you can turn to Figure 3, what is that? 15:19:44

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

DATCARD SYSTEMS, INC., a California corporation, Plaintiff, vs. PACSGEAR, INC., a California corporation, Defendant.	Case No. SACV 10-1288 DOC (VBKx) (PER PROTECTIVE ORDER SECTION 11 THIS TRANSCRIPT HAS A TEMPORARY "CONFIDENTIAL - OUTSIDE COUNSEL ONLY" DESIGNATION FOR A PERIOD OF 14 DAYS AFTER THE DEPOSITION IS RECEIVED.)
COMPLETE CAPTION ON NEXT PAGE.	

DEPOSITION OF

ALAN H. ROWBERG, M.D.

LOS ANGELES, CALIFORNIA

DECEMBER 16, 2011

ATKINSON-BAKER, INC.
COURT REPORTERS
(800) 288-3376
www.depo.com

REPORTED BY: SUSAN M. PATTERSON, CSR NO. 2448
FILE NO.: A50BB63

CONFIDENTIAL

ALAN H. ROWBERG, M.D. A50BB63 DECEMBER 16, 2011

A. A structured set of data held in a computer, especially one accessed in a variety of ways.

Q. Do databases have schemas? Do you know what a schema is?

A. They may. It's a convenience to the programmer to use the database schema. There are databases that don't have one.

Q. And how do you distinguish between a database that has a schema and a database that doesn't have a schema? Is there terminology used?

A. Commonly a more complicated database uses a database management system such as the commercial systems offered by Oracle and Microsoft Access and will have more formal computer structure as you place the database in the computer. A simpler database might simply be a series of data items that repeat for each entry in the database and will not need the formal structure that a larger and more complicated database has.

Q. What do you mean by that, "repeat for each entry"?

A. For instance, a payroll database might have the employee's name, the employee number, and the number of hours worked, and for each employee

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that set of data would be repeated.

Q. Thank you. And, again, that would be part of the schema for that database?

A. In a simpler database I don't know that you say that that's a database schema. It may be just a description of the data format that's being used. In the more complicated databases the tables are given names and they're handled in a formal name by the computer and queried by their table name and data element name.

Q. Do you know how the databases used in the Pacsgear product are labeled or named?

A. I don't know if they use one of the commercial database systems or if they've created their own. I don't remember looking at any of their... I don't remember clearly looking at any of their data tables. I may have looked at some of their data tables to see what fields they save associated with auditing. I would have done this with the assistance of one of their programmers who would have then called up the data table or file, and I may not have noticed its name.

Q. Which programmer did you work with there?

A. I don't remember his name.

Q. Okay. What's the difference between a database and a file system?

A. A file system is handled by the operating system and stores files, obviously. It does not have the structure that a database has. For instance, the files might be totally different from each other and not be a repeat of the previous file. In a database the successive records are in some way structured and a repeat of the previous data set.

Q. Is another difference between a database and a file system the way they're searched?

A. I don't know that method of searching is very tightly coupled with the concept of a database. Some of them can be retrieved in a simple linear manner and not searched randomly. Typically with disk files you need to be able to search randomly since the file structure allows for that, with less emphasis on sequential access.

Q. Okay. Again, I have to break that up from here. You said "disk" and "sequential." What do you mean by disk access?

A. In a file system typically you are accessing disk files and you need a random access capability to get the file that you've specified.

Q. What do you mean "random access capability"?

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A. Can you repeat that?

Q. I'm sorry. What do you mean by "random access capability"?

A. Selecting one file out of the file system because you know its name and getting only that one file without having to read the entire file system one file at a time to find the one you're looking for.

Q. And how is this different than searching a database?

A. It's the same as one type of database search which would be random access to a record. There are other ways of accessing databases that are also commonly used, such as sequential access. If I were looking for Figure 1 in this document I could start at page 1 and page all the way through. That would be sequential. Or you could tell me turn to -- unfortunately the pages aren't numbered -- but page 57, and I would go down to page 57 and immediately find that.

Q. Okay. And the image server database that's shown in Figure 1, what type of database is that?

A. I've seen only a portion of the source code for the MediaWriter and not --

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BY MR. HOLBROW:
Q. It's all part of Claim 9, correct?
A. Yes. The limitation on page 17 specifies the database being used to store the data, not the database from which the data are retrieved.
Q. Okay. So your interpretation of the claim is that the database shown on page 17 at line 11 is not the same database shown in page 20, line 9?
MR. STEWART: Object. I think that mischaracterizes the testimony.
But you can answer the question.
THE WITNESS: I missed the grounds for objection.
BY MR. HOLBROW:
Q. You can answer. He gets to object. I'm sorry, I should have said that in the beginning. Mr. Stewart may throughout the deposition make objections. They're for the record. And unless he tells you not to answer, you can go ahead and respond.
MR. STEWART: And my objection was simply I thought he was mischaracterizing your testimony in his question. But you certainly should go ahead and answer the question to the best of your ability.
A. (Reviews document.)

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Well, it's been over a month since I read all of Claim 9 as a unified body, so when I'm skipping around I'm at risk of confusing myself.
If some data came from an HL7 feed and other data came from a DICOM connection, they could be internally stored in either one or two databases. And when searching the storage, that decision in architecture would affect how many databases were involved.
Q. Okay. My question -- I'll help you out.
MR. HOLBROW: We'll mark this next in order. It's 215, the '164 patent.
(Defendant's Exhibit 215 was marked for identification.)
BY MR. HOLBROW:
Q. If you go all the way to the end of that document, it has the claims.
A. Okay. And so this is the reexamination certificate, and the claims begin numbered with 9.
Q. Well, we're going to be looking at Claim 9. The claims actually begin with 1, but the change claims subject to reexamination are included here. So these are the latest and greatest versions of these claims.
A. Okay.

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Q. So the question is, the Claim 9, the second limitation starts off:
A database...
And the fourth limitation states:
A search module configured to search the database.
My question is, is it your understanding that the database identified in the second limitation can be different than the database identified in the fourth limitation?
A. (Reviews document.)
Because it has defined "database" and then says "the database," I think it's referring back to the same one. So I would think it would be the same.
Q. What is your understanding of the meaning of the term "server" as used in the patents?
A. "Server" may be the least precisely defined term in all of computer science. Some people mean hardware: "I will buy a server and put it in the basement of the hospital." Other people will talk about the software component and say the software is the server.
In its most general way, it's a system that provides services to computers. It may be the

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same computer. You may have a laptop that has both a web server and a web client on the same computer. That may occur in many other environments. Or they may be different computers where the PACS system may have a DICOM image server that serves up images to other computers connected in the network configured as viewers.
Q. And as it's used in the patent, how would you -- how would you define "server" based on the patent?
A. As I recall, it's the software kind of server providing services to a computer or typically computer software, other modules that typically reside in the same computer in our environment.
Q. And have you used the MediaWriter product?
A. I used the one that had been purchased by DatCard in their facility.
Q. Okay. And what did you do when you used it?
A. We exercised all of its functions one at a time going through, looking at -- burned a CD, looked at auditing, the way the labeling was done, the results of the auditing. We went into another room and opened a web server, connected to it remotely, and observed a remote browsing terminal

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ALAN H. ROWBERG, M.D. A50BB63 DECEMBER 16, 2011

Q. And is the portion that he highlighted and underlined on that page the same sentence that you came up with? 10:32:04 10:32:05 10:32:10
A. It is. 10:32:12
MR. HOLBROW: Why don't we take a break. 10:32:13
VIDEOGRAPHER: Watch your microphones when you get up. Now going off the record. The time is 10:32 a.m. 10:32:15 10:32:18 10:32:21
(Recess from 10:32 a.m. to 10:40 a.m., after which Mr. Martin is not present in the deposition room.)
VIDEOGRAPHER: Now back on the record. The time is now 10:40 a.m. 10:40:06 10:40:07
Counsel? 10:40:10
BY MR. HOLBROW: 10:40:11
Q. You're all set? 10:40:11
Okay, when we broke you were referring to a sentence in column 2 that referred to "medical exam data." Do you recall that? 10:40:13 10:40:16 10:40:20
A. Yes. 10:40:23
Q. And is there anything in the patent that teaches that the medical exam data includes HL7 reports or Mitra broker reports? 10:40:26 10:40:32 10:40:35
A. I don't recall either the phrase "HL7" or "Mitra" -- 10:40:43 10:40:46

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Q. Okay. 10:40:49
A. -- in the patent specification. It could well be there. 10:40:49 10:40:59
Q. And you agree that the HL7 reports and the Mitra broker reports are text reports? 10:41:04 10:41:09
A. Yes. 10:41:11
Q. Not medical images. 10:41:11
A. Correct. 10:41:12
Q. And do you recall -- you've gone through it several times now already. Is it fair to say that there's nothing in the specification that refers to HL7 reports, Mitra reports, or any type of text report? 10:41:20 10:41:25 10:41:27 10:41:29 10:41:34
A. I didn't see that phrase as I was skimming through. 10:41:37 10:41:39
Q. I'm not talking about a specific phrase. I'm talking about the general topics of HL7 reports, Mitra reports, or any text reports. 10:41:40 10:41:42 10:41:46
A. Only that one sentence that I found. That's the only sentence I found that relates to that. 10:41:48 10:41:50 10:41:53
Q. And that's the column 2, line 6? 10:41:53
A. Correct. 10:41:58
Q. Okay. And is there anything in the patent, other than the use of the term "medical exam 10:41:59 10:42:07

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data," that suggests that that term means text reports or HL7 reports or any Mitra reports? 10:42:11 10:42:16
A. I haven't seen anything else, no. 10:42:27
Q. And if you turn to Figure 5 of the '164 patent, and in box 178 it says "select exams"? 10:42:31 10:42:44
A. Yes. 10:43:02
Q. Do you see that? Is that referring to the exam data that you mentioned in column 2? 10:43:02 10:43:06
A. In our PACS system I'm used to thinking of exams as including reports. Here the following block says: 10:43:32 10:43:37 10:43:42
Find related image data.
And so I believe here these two blocks are related to images rather than to nonimage data described in column 2. So I think this "selected exams" refers to the images for that patient. 10:43:47 10:43:50 10:43:58 10:44:04
Q. Is there any other place in the patent that talks about -- that further defines what the exam data is, besides Figure 5? 10:44:08 10:44:12 10:44:17
A. The word "exam" is not used frequently in this specification. The phrase "image data" is usually used instead of exam, and so I guess the place I'd expect to see it is where there's a 178 item in the long section on the following page. 10:44:28 10:44:32 10:44:45 10:44:52 10:44:58
Q. Maybe column 8, line 38. It looks like 10:45:16

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178 is highlighted. 10:45:24
A. So in 178 they're selecting exams, and I would take that to mean the images. And then the following three lines: 10:45:38 10:45:41 10:45:45
The user is then asked in step 180 if he or she desires to find related data of that patient for comparative study.
Their "related data" does not have the word "images." That might mean HL7 reports. It also might mean comparative exams and be referring to image data. 10:45:52 10:45:55 10:46:00 10:46:08
Q. Okay. So you're saying that the next -- that last sentence where it says: 10:46:10 10:46:13
The user is then asked in step 180 if he/she desires to find related data of that patient for comparative study.
The use of "related data" there could mean reports? 10:46:23 10:46:27
A. Because it doesn't say "image," it's at best vague. 10:46:28 10:46:34
Further down there's "related data storage," field 254. That goes back to a different figure, I think. 10:46:40 10:46:44 10:46:48
(Reviews document.) 10:46:59

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15 (Pages 54 to 57)

That's related to something else. 10:47:01
Q. Okay. If you can turn back to the 10:47:11
sentence we were looking at in column 8: 10:47:17
The user is then asked in step 180
if he/she desires to find related data
of that patient for a comparative
study.
Do you see that sentence? 10:47:29
A. Yes. 10:47:31
Q. So I'm clear, you said that the use of 10:47:32
"related data" there is vague and it could mean -- 10:47:37
A. It's vague because there is the word 10:47:41
"comparative study" there. I would think it would 10:47:43
be comparative images. 10:47:47
Q. So when they use "related data" it refers 10:47:50
to images? 10:47:52
A. In this case I think it's images. In 10:47:59
other cases it may mean reports, and I believe the 10:48:01
phrase is, unfortunately, vague. 10:48:07
Q. Okay. 10:48:09
A. At least from my medical understanding. 10:48:17
From a legal sense of view it may be something 10:48:19
totally different. 10:48:23
Q. All right. So from a medical 10:48:24
understanding, the terms that are used in the 10:48:26

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patent: "related data," "related medical image 10:48:29
data," "selected medical image data," those are 10:48:31
vague in the medical community, but we need to look 10:48:37
at the patent to figure out what they mean? 10:48:39
A. Yes. 10:48:42
Q. And in fact if you turn to Figure 5 in box 10:48:46
180, it confirms your belief there that "related 10:49:00
data" referred to "related image data," correct? 10:49:05
A. It seems to do that. I'm remembering the 10:49:16
phrase "related medical image data" which said data 10:49:24
related to the medical images. Here the word 10:49:30
"medical" is missing. I'm wondering if the authors 10:49:32
meant the same thing, and I have a hard time proving 10:49:36
it one way or the other. 10:49:39
Q. Another ambiguous term? 10:49:43
A. Unfortunately. 10:49:45
Q. Can you find anywhere in the specification 10:50:05
where you're confident that "related data" means 10:50:07
text reports? 10:50:11
A. Not other than in -- was it column 2? 10:50:17
Q. Column 2, that doesn't use "related data," 10:50:33
does it? That's the sentence we've been looking at. 10:50:37
A. It says medical exam data that are 10:50:42
related. 10:50:45
Q. Okay. 10:50:46

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A. And it doesn't say comparison, which I 10:50:47
would expect it to do if it were comparison images. 10:50:49
So I believe this is related to the reports. 10:50:53
Q. And does the term "medical exam data" come 10:51:00
up at all in the claims? 10:51:03
A. I don't remember it. 10:51:10
Q. So if there's nothing in the patent 10:52:03
specification about acquiring text reports, then is 10:52:19
it fair to say that one skilled in the art wouldn't 10:52:26
be able to learn from the patent how to go to the 10:52:30
various brokers and get the text reports? 10:52:35
A. If it's described clearly in the claims, 10:52:40
then that may be adequate. 10:52:43
Q. Okay. I'm talking about the 10:52:45
specification, though. 10:52:47
A. It would certainly be difficult without 10:52:59
something else, either the claim or -- I don't know 10:53:03
what else it would be. 10:53:12
Q. Okay. So just solely based on the 10:53:13
specification, one skilled in the art wouldn't be 10:53:16
able to know how to acquire the reports, but 10:53:19
something in the claim? 10:53:24
Why don't we turn to the claim and see if 10:53:25
there's anything in the claim that you think 10:53:28
facilitates that. I think the claims are on the 10:53:31

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very back pages there. 10:53:33
A. Okay. And I know that some of the patents 10:53:35
focus more on searching for reports than others, and 10:53:47
I don't know that '164 is one that particularly 10:53:50
focuses on that. 10:53:53
Q. Okay. Well, let's start with this one. 10:53:54
A. It may be that there's a different patent 10:53:58
that... 10:54:02
(Reviews document.) 10:54:03
So Claim 9, as they're numbered here, the 10:54:27
fourth element. 10:54:39
Q. Um-hmm. 10:54:40
A. As I believe they're called: 10:54:41
A search module configured to search
the database for related medical image
data.
And that's the phrase that I believe 10:54:49
matches HL7 reports that's related to the selected 10:54:52
medical image data. 10:54:57
And then three elements after that: 10:54:59
The related medical image data
recorded in the standard medical
imaging format.
This would be images because DICOM is the 10:55:08
standard medical imaging format described in the 10:55:13

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ALAN H. ROWBERG, M.D. A50BB63 DECEMBER 16, 2011

document.

Q. Okay. So in this claim, anyway, the term "related medical image data" necessarily refers to images?

A. It seems to.

(Reviews document.)

Q. And would you agree that the same terminology, "related medical image data," would have the same meaning in the patent, or would there be a circumstance where it might have a different meaning, the same four words?

A. I would rather it didn't have a different meaning, but I'd have to look at the other claims in context. And I believe that there is a context that led me in a different direction in a different patent.

Q. Okay. In a different patent? Okay.

A. Not in this patent.

Q. Okay.

A. I don't see it in here.

Q. Okay. So it's fair to say in this patent anywhere in the claims the term "related medical image data" appears it's referring to images?

A. It seems to, yes.

Q. Can you identify anyplace that it doesn't?

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A. In this patent, no.

Q. Okay, let's turn to the '597 patent, which has been previously marked as Exhibit 214.

A. Yes.

Q. Okay. If you can go to Claim 1, do you have that in front of you?

A. Yes. And I'm in column 9.

Q. All right. The first element there says:

Receiving via computer-implemented interface request for medical data related to the patient.

Do you see that?

A. Yes.

Q. Okay. And then the second sentence says that:

Automatically searching a first computer...

The second limitation, I'm sorry, says:

Automatically searching a first computer database via first database interface for a first set of medical imaging data related to the patient based on a received request.

Do you see that?

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A. I do.

Q. So is it your understanding someone's at a computer receiving medical data in the first limitation, and the second limitation discusses that it's going to a database to search for that medical data?

A. Yes.

Q. So in that context "medical data" and "medical imaging data" are synonymous.

A. They seem to be.

Q. And then the next limitation says:

Automatically retrieving the first set of medical imaging data related to the patient.

Do you see that?

A. Yes.

Q. And then the -- I guess we're down to the fourth limitation. It's a longer claim.

Automatically searching based on a received request a second computer database via a second database interface for additional medical data also related to the patient wherein the second interface is different from the first interface.

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Do you see that?

A. Yes.

Q. And this is again referring to the first limitation that uses "medical data," correct?

A. It has the same phrase, except it has the word "additional" there.

Q. "Additional," okay.

A. And makes me think it's different than "imaging data." More broad. "Imaging" being a subset -- "medical imaging data" being a subset of "medical data."

Q. Okay.

A. And the fact that it's a different interface makes me wonder if this is still images.

Q. And is there anything in the patent that would suggest that this term means anything but images?

A. The fact that it's a different phrase.

Q. Okay.

A. At least makes me wonder. And it is not specific as I would have liked to see in a document.

Q. Okay. So you aren't sure what it means?

A. And I almost wonder if it's a legal term instead of a medical term because it's out of my normal vocabulary.

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Q. Okay. Earlier we agreed that, in reviewing the first two limitations, that "medical data" was synonymous with "medical imaging data," correct? 11:02:13 11:02:28 11:02:31 11:02:36
A. I'm bothered by the fact that the terms are different, and it may be that it is a subset. That is, "medical imaging data" may be a subset of "medical data." 11:02:38 11:02:39 11:02:52 11:02:55
Q. And what in the patent specification leads you to believe that there's a difference between "medical data" and the "medical imaging data"? 11:02:56 11:02:59 11:03:02
A. The fact that different phrases are used. The author would have had a reason for using different phrases -- 11:03:06 11:03:08 11:03:11
Q. Okay. 11:03:13
A. -- in the same claim. 11:03:13
Q. Okay. When we look back at column 8, line 28, the author of the patent is defining step 180. Do you see that? 11:03:15 11:03:53 11:04:05
A. Yes. 11:04:06
Q. And he uses the term "related data" there? 11:04:07
A. Yes. 11:04:10
Q. And then in the Figure 5 we looked and it actually meant -- the author meant "related image data"? Is that a fair summary? 11:04:10 11:04:15 11:04:20

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A. I think -- 11:04:26
Q. Yeah, feel free to look. 11:04:28
A. I think so. 11:04:32
(Reviews document.) 11:04:33
So I see "related data" in column 8 for step 180, and then the label on the box says "related image data." 11:04:55 11:05:01 11:05:04
Q. So in that case -- 11:05:06
A. So it seems like they're the same. 11:05:08
Q. Okay. And is there any reason that that wouldn't carry through to the claims where they use "medical image data" and "medical data"? 11:05:10 11:05:14 11:05:20
A. My concern is that the claims were written at a later time than the specification, and the author may have, without realizing it, changed terminology sets. 11:05:25 11:05:28 11:05:31 11:05:36
Q. Okay. 11:05:38
A. And I wish he wouldn't do that, but if he did and if what he said in the claim was clear to the patent examiner, then I'm not going to argue with the patent examiner. 11:05:40 11:05:46 11:05:49 11:05:54
Q. Okay. Maybe I can just -- we looked at the Figure 5 in column 8, and the author in that situation in one point identifies "related data" and then, referring to the exact same thing, "related 11:05:56 11:05:59 11:06:03 11:06:11

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image data," correct? 11:06:14
A. Yes. 11:06:16
Q. So there's no reason that the same wouldn't be true in Claim 1 where at one point the author uses "medical data," at another point "medical imaging data," and then later "medical data"? 11:06:17 11:06:22 11:06:26 11:06:31 11:06:37
A. That's certainly a reasonable argument. Where it's in a claim, I would be happier to let the judge construe the term and have him tell me they're the same or different. 11:06:46 11:06:49 11:06:56 11:06:59
Q. At some point the judge will get involved. I'm just asking for you. 11:07:01 11:07:03
A. From the standpoint of English grammar, it seems that the terms do change from time to time. 11:07:05 11:07:09
Q. I'm not sure that answered my question. 11:07:12
MR. HOLBROW: Can you read back the question. 11:07:16 11:07:16
(Record read by the reporter as follows:
So there's no reason that the same wouldn't be true in Claim 1 where at one point the author uses "medical data," at another point "medical imaging data," and then later

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"medical data"?)
A. And I guess my answer is yes. 11:07:40
Q. Okay. And if, as we discussed, "medical data" is defined to be synonymous with "medical image data," then that would not include text reports, correct? 11:08:03 11:08:08 11:08:12 11:08:16
A. Correct. 11:08:18
Q. Okay. Turning back to -- you're probably there already -- the second limitation uses the term "a first computer database." 11:08:43 11:08:46 11:08:51
A. Yes. 11:08:54
Q. What database is that referring to in the MediaWriter? 11:08:56 11:09:02
A. This would depend on the environment. It might be the modalities themselves or a PACS system. The user has received the request for the data related to the patient, so this was some sort of patient-level selection. So then you'd be going back to the PACSs or the imaging modalities, depending on the configuration. 11:09:29 11:09:32 11:09:41 11:09:44 11:09:46 11:09:52 11:09:54
Q. And when you say "imaging modalities" you're referring to? 11:09:57 11:10:00
A. CT or MRI scanners, for example. 11:10:01
Q. Okay. And then the fourth limitation refers to a second computer database. 11:10:16 11:10:22

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18 (Pages 66 to 69)

these locations, correct? 11:24:12
A. Yes. 11:24:13
Q. Okay. 11:24:18
A. Or the system manager. Perhaps not the end user on a day-to-day basis. 11:24:19 11:24:24
Q. And you mentioned the local database, and that's to -- if there's HL7 reports stored on the local database, that would be the reason for searching the local database? 11:24:42 11:24:45 11:24:49 11:24:53
A. Yes. 11:24:55
Q. Okay. And the way the MediaWriter searches for images is to go to the PACS. Is that your understanding? 11:24:56 11:25:12 11:25:16
A. Or the imaging modalities such CT or MRI. 11:25:17
Q. Okay, thank you. And you agree that there's no way for the MediaWriter to search its own local hard drive for images; it has to go to the PACS or modality. Correct? 11:25:25 11:25:40 11:25:43 11:25:48
A. When burning the CD it has to use the images that it has already stored when it's ready to burn. 11:25:56 11:26:00 11:26:03
Q. Okay. But I'm talking about searching first. 11:26:04 11:26:06
A. That isn't really searching. That's just retrieving them. It knows where they are. It 11:26:08 11:26:10

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doesn't have to search for them, fortunately. 11:26:16
Q. Okay. So the only way the MediaWriter searches for images is by going to the PACS or the modalities? 11:26:18 11:26:20 11:26:24
A. Yes. 11:26:24
Q. And you'd agree that the PACS and modalities are separate and different from the MediaWriter, correct, in terms of what Pacsgear sells? 11:26:57 11:27:00 11:27:03 11:27:12
A. Yes, the MediaWriter is separate from the PACS. 11:27:13 11:27:16
Q. And what components comprise the MediaWriter? 11:27:16 11:27:20
A. In terms of hardware, it's a standard computer with keyboard, mouse and screen. And then in terms of disk production, I believe they're buying one of several different models from another company and configuring it as a hardware package. And then the software would be their application and the helper programs associated with that. Some companies run the DICOM service to get images as a separate program and other companies embed it in the main program. 11:27:22 11:27:26 11:27:31 11:27:38 11:27:41 11:27:45 11:27:49 11:27:54 11:28:01 11:28:04
Q. Is it fair to say if we were to construe "medical data" in the fourth limitation to mean 11:28:59 11:29:04

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"medical image data" as we previously discussed, that this limitation wouldn't be satisfied by the MediaWriter? 11:29:07 11:29:14 11:29:18
A. It's my understanding that the MediaWriter can be connected to do different PACS systems, so that would appear to satisfy this limitation. 11:29:32 11:29:35 11:29:38
Q. Okay. And if it's -- do you know how it's connected, whether it's part of the initial search you can select a different PACS? 11:29:41 11:29:50 11:29:52
A. To connect to a PACS or a medical imaging modality you have to program both the PACS and the device with three things: an application entity title, an IP address, and a port number. So that is typically done at the time of installation. We decide how many PACSs you want to connect to, find out where they are, get the appropriate AE title and other information. So it's part of the original setup. 11:29:56 11:30:00 11:30:06 11:30:11 11:30:15 11:30:19 11:30:22 11:30:25 11:30:28
Q. Okay. And that's what we were discussing in the second limitation, that it searches a PACS database? 11:30:31 11:30:36 11:30:43
A. Yes. And if -- in the fourth limitation if you're searching for a second PACS or some other device not connected to a PACS. 11:30:46 11:30:50 11:30:54
Q. Okay. Like a modality? 11:30:56

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A. It could be a modality. It could be a device that generates DICOM-compatible images and makes them available. Or it could be a mini-PACS, an ultrasound mini-PACS or the mammography mini-PACS that we have, for example. 11:31:00 11:31:03 11:31:13 11:31:18 11:31:24
Q. If you can explain how the search in the fourth limitation is satisfied if there's HL7 reports for the sought-after reports? 11:32:29 11:32:36 11:32:40
A. The HL7 reports come streaming in as the radiologist dictates and approves the reports. They're stored somewhere on the MediaWriter in what I would call a database as a structured set of data, and then the MediaWriter would search that database for matching information: patient name, identifiers, study identifiers. 11:32:47 11:32:52 11:32:55 11:32:59 11:33:03 11:33:09 11:33:15
Q. Okay. And I think you -- for that one you identified the -- or in that list you provided you identified the local hard drive. Is that...? 11:33:31 11:33:41 11:33:46
A. I don't know the internals so I don't know where it's stored. Conceivably it could be stored in the memory of the computer. You would tend not to do that because you would lose it if there were a power failure or if the device were turned off. So the hard drive is commonly a storage place. 11:33:55 11:33:57 11:34:01 11:34:04 11:34:09 11:34:14
Q. And then you're referring to a specific 11:34:17

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ALAN H. ROWBERG, M.D. A50BB63 DECEMBER 16, 2011

Q. Well, wherever it appears in Claim 1, but it does appear in the fourth element, yes.
A. And the answer is yes.
Q. So in this case "related data" in Claim 1 is synonymous with "related medical image data." Is that a fair statement?
A. (Reviews document.)
I have trouble with that because in normal English language the addition of an adjective implies some sort of restriction. You might have beautiful colors used in a painting, but if you talk about beautiful pastel colors in the painting you're only talking about the pastel tones. So it qualifies it to a narrower set of elements.
So here when we say "related data" in element 4 of 1 and then later on have a more specific term, "related image data," or "related medical image data" in this case, because of the added adjectives, I think they are, or nouns, that qualify it, it raises my concern that this actually means a more specific term. And because these terms are not on the tip our tongue in the medical environment, I don't have a visceral feeling about the nature of that qualification.
But at this point I'm concerned that

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"related data" is probably broader and may be including any type of relationship, which would be reports and images.
Q. Okay. And since you're not sure what it means, or one skilled in the art necessarily understands what it means, you would look back to the specification to try to get some guidelines?
A. That is one place I'd look. I'd look at other claims to get the context of the invention. And in other environments I'd look to the judge for claim construction.
Q. And if we were to go back and look at the specification to help us understand what "related data" meant, or what the "related data" means, I think we've done that exercise and it appears that the patent drafter has used "related data" and "related medical image data" to mean the same thing.
A. And that same thing is probably the broader concept of both images and reports. In the lack of something where I can really narrow it down, it appears in a lot of settings it's the broader.
Q. And can you show me again was there anything in that specification that recognizes that it is something other than images?
A. The fact that the terminology changes make

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me think that it's not specific. In some cases it's being used in the context of an image and "related data" clearly means an image. In other cases there might be a different context and the same phrase might mean something else to this particular author, who is not as specific as I would have liked.
Q. Okay. And where is it used -- where is the term "related data" used in the specification other than to identify an image? You can look at any of the specifications.
A. Yeah. Unfortunately I've spent much more time looking at claims than the specifications. So in the claims it's much easier to find.
There are other things that we can't find in the specification, like the word "timeout." And I --
Q. We're going to get to that.
A. I being a country doctor don't understand how this can be, and at this point I probably ought to say I don't know where to find that in the specification because I suspect I can't.
Q. Well, I'm entitled to ask you questions because you've come up with an opinion on these things, and I need to know what the basis for that was.

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A. The answer is I probably can't find it in the specifications. I can only find it in the claims.
Q. Okay. So it's fair to say nowhere in the specification does "related data" mean -- let me turn it into a positive. Everywhere in the specification when "related data" is used it's referring to an image; is that correct?
A. No. When you make it a negative it's no longer true. The way the Venn diagrams interact, these are overlapping circles.
Q. Okay. Is there anything in the specification that teaches that "related data" can mean anything other than images? And, if there is, please find it.
A. I don't know of a citation that teaches that.
Q. And you're more than welcome to look. You're confident you won't find anything?
A. I believe I tried this morning and I couldn't find that.
Q. Okay. All right. Turning back to the claims of the '174 patent, again, we've looked at claim 5 which uses "related medical image data," correct?

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they're using in the figure. 13:12:17
Q. Okay. So they might have just used "related data" as shorthand for "related image data"? 13:12:19
A. Well, it says "with the additional option," as if it might be something else. 13:12:38
Q. Well, isn't that what's shown in Figure 5? 13:12:44
A. (Pause.) 13:12:47
Q. Decision point 180 -- 13:12:47
A. I think so. I think that "related data" is referring to images because it's still on Figure 5 where they're talking about images. 13:13:04
Q. Okay. So in the text of the specification they just shortened "related image data" to mean "related data"? 13:13:11
A. Yes. 13:13:18
Q. Okay. 13:13:30
A. Line 36, again "related data." 13:13:31
Q. All right. And that's still referring to Figure 5, correct? 13:13:47
A. I believe so. 13:14:02
Q. So, again, that's just a shorthand for "related image data," correct? 13:14:06
A. Yes. 13:14:13
Then in line 40 is another occurrence of 13:14:25

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"related data," and in the following sentence they go on to "related medical image data." And at that point I believe they're using the broader term. 13:14:28
"Related data" is on 45 also. 13:14:44
Q. I'm not sure what you meant by "the broader term." Is it fair to say that anytime they use "related data" it's just shorthand, abbreviating "related medical image data"? 13:14:46
A. Every occurrence I have found suggests that. But here it says "related medical image data," bringing in another term. 13:15:02
Q. Yeah. For that one they decided not to go shorthand apparently? 13:15:12
A. Or they mean something else. 13:15:18
Q. What else would they mean? 13:15:23
A. Reports, HL7, Mitra. 13:15:25
Q. What in the specification causes you to -- we already decided, agreed that HL7 Mitra reports aren't mentioned anywhere in the specification, correct? 13:15:31
A. (Pause.) 13:15:48
Q. Is that true? 13:15:48
A. That's true. 13:15:49
Q. Okay. 13:15:50
A. But I don't know what that means. It may 13:15:50

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mean inattention, such as with timeout. 13:15:54
Q. But everyplace we found in the specification where it says "related data" it appears that it is shorthand for "related medical image data." Is that fair? 13:16:01
A. So far it certainly is. 13:16:13
Okay, so that takes me to the end of the description. 13:17:01
Q. Okay, I think we made it through, then. So to summarize, everywhere you found the term "related data" it was shorthand for "related medical image data"; is that correct? 13:17:04
A. Yes. 13:17:18
Q. And when we use the term "related medical image data" we're referring to images only, correct? 13:17:18
A. I probably -- that's right. Would you ask the second question again? 13:17:31
Q. That's fine. The term "related image data" refers to images only, correct? 13:17:35
A. We didn't analyze that term. In the claims I don't think that's the case. 13:17:47
Q. Okay. I'm asking just on -- on the specification is there anything -- from the term "related image data," doesn't that necessarily mean, refer to images? 13:17:52

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A. Yes. 13:18:05
Q. Okay. All right. Turning to -- okay. And it -- and "related image data" necessarily excludes anything that's not an image, correct? 13:18:06
MR. STEWART: Object. Do you mean in the specification or the claims? 13:18:33
BY MR. HOLBROW: 13:18:38
Q. The interpretation of the term "related image data." 13:18:39
A. I haven't gone -- I don't remember going through the specification for that exact phrase, and I wish the author were more precise. And it's difficult for me to generalize without having searched for every occurrence. 13:18:59
Q. Okay. Do you have any reason to believe that the term "selected medical image data" means anything but images? 13:19:24
A. If you do a DICOM query-retrieve and you get images and a structured report and you select them, then it also means the report. 13:19:47
Q. Okay. But that would be in a DICOM object format, correct, not in a text format? 13:20:02
A. Yes. 13:20:18
Q. Okay. 13:20:18
A. And I'm trying to think if there are other 13:20:19

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examples. I'm afraid I don't remember the question. 13:20:23
Q. Okay. We're talking about image. Is a... 13:20:36
A. Selected... 13:20:40
Q. Selected medical image data. Is a structured report an image? 13:20:41 13:20:47
A. Unfortunately "structured report" is not defined clearly. There is a dose structured report in DICOM, which can be displayed as an image in the CT scanner or in PACS, that gives dose information. It's a structured report and it's viewed as an image. 13:20:58 13:21:05 13:21:14 13:21:19 13:21:24 13:21:27
Q. I guess maybe we can back up a little bit. We talked earlier about one skilled in the art. You gave a definition of -- 13:21:28 13:21:30 13:21:34
A. Yes. 13:21:37
Q. -- what the background and experience level of one skilled in the art would be. Do you remember that? 13:21:38 13:21:39 13:21:43
A. Yes. 13:21:44
Q. If one skilled in the art saw the term "selected medical image data" in connection with this patent, would they find that it meant images only? 13:21:45 13:21:48 13:21:52 13:21:57
A. I believe they will. 13:22:06
Q. And that is because, to one skilled in the 13:22:17

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art, "medical image data" they would think of as images, correct? 13:22:20 13:22:28
A. Images plus the demographics: patient name, things like that, which are actually text items, unfortunately. 13:22:36 13:22:39 13:22:42
Q. That accompany the image, correct? 13:22:44
A. Yes. 13:22:48
Q. So one skilled in the art seeing "image data" would think that it only meant -- it only referred to images to the exclusion of other things, correct? 13:22:57 13:23:00 13:23:05 13:23:08
A. Yes. 13:23:14
Q. And turning to claim -- I think we're on Claim 9 of the '164 patent. 13:23:14 13:23:19
Okay. Is the limitation there, it's the third limitation: 13:23:50 13:23:58
Plurality of browsing terminals configured to receive a user selection that defines selected medical image data.
A. Yes. 13:24:11
Q. And is a MediaWriter a browsing terminal? 13:24:11
A. The keyboard and screen combination behave as if they were browsing terminal accessing the application. Whether that's implemented as client 13:24:30 13:24:36 13:24:39

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server inside the software the way the remote browsing terminals are or whether it's implemented differently I don't think I know. 13:24:47 13:24:51 13:24:53
Q. Okay. My question, though, was whether the MediaWriter workstation is a browsing terminal. 13:24:57 13:25:00
A. I think it contains a browsing terminal. It contains other things such as database and interfaces and whatnot. 13:25:05 13:25:09 13:25:13
Q. Okay. So if this claim just said: 13:25:17
A browsing terminal configured to receive a user selection that defines selected medical image data.
Would the MediaWriter satisfy that? 13:25:28
A. I would think it would. 13:25:30
Q. And if there were two MediaWriters side by side connected to the same PACS, would that satisfy the limitation of having a plurality of browsing terminals? 13:25:31 13:25:35 13:25:40 13:25:43
A. It would for the hospital but not necessarily for the MediaWriter. But you'd probably consider each MediaWriter separately. This may be a legal distinction rather than a medical one. 13:25:55 13:25:57 13:26:00 13:26:04
Q. Okay. Well, I'm asking for your interpretation. 13:26:07 13:26:11
A. I would think that if you had two 13:26:12

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MediaWriters you would say each of them only had one browsing terminal so neither of them had a plurality. You simply had two of them, two independent instances of a MediaWriter. 13:26:16 13:26:21 13:26:23 13:26:28
Q. So would that satisfy a claim -- 13:26:32
A. That would not be a plurality. 13:26:34
Q. If you had a MediaWriter that's connected to a PACS and then another MediaWriter that was connected to the PACS and the first MediaWriter's hard drive, would that constitute a plurality of browsing terminals? 13:26:46 13:26:50 13:26:56 13:26:59 13:27:04
A. I would say yes because they're connected. 13:27:06
Q. And the MediaWriter is sold as a single workstation, correct? 13:27:23 13:27:30
A. The advertising says that it can be used with multiple browsing terminals, so there is a single workstation but it has support for other user interface devices, web browsers. 13:27:38 13:27:43 13:27:46 13:27:51
Q. But as it's sold it doesn't satisfy this limitation of Claim 9, correct? 13:27:54 13:27:57
A. As it's shipped it's not configured that way. But their help desk can change that configuration for the user. 13:28:06 13:28:09 13:28:15
Q. So it's only if the user changes the configuration would the MediaWriter be covered under 13:28:16 13:28:20

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Q. Okay. So looking at the next claim, we can go to claim 15, the term "database" appears in limitation 2 and in limitation 4.

A. (Reviews document.)

Q. Do you see that?

A. Yes.

Q. Okay. And in terms of what databases in the MediaWriter satisfy that limitation, would it be the same for distinct databases that we discussed earlier: the local hard drive where the images are stored, the database where the HL7 reports are stored, the Mitra broker, and a second PACS?

A. I believe that claim 15 is a restatement of Claim 9 with a modification at the end, so all of the words are the same and all of the conclusions are the same.

Q. Okay. And I just want to do it for this claim. So is it accurate to say that the four distinct databases that are associated with the MediaWriter, in your opinion, that satisfy the "database" term in claim 15 are the local hard drive where images are temporarily stored, the HL7 database where the HL7 reports are stored, a second PACS, and a Mitra broker?

A. And depending on what assumptions we make

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about the database in claim 2 and whether it has to be inside the MediaWriter. You asked about two different cases. So the PACS and the Mitra broker images might conceivably be inside the MediaWriter as well as outside.

Q. Okay. So the four databases are the local hard drive where the images are stored, the HL7 database where the HL7 reports are stored, and the second PACS, and the Mitra broker?

A. Whether they are inside or outside.

Q. Whether they are inside or outside, those are the four distinct databases?

A. Maybe "distinct databases" isn't the right term because the information sources might all be stored in the same database, so it might not be a distinct database. If we define "database" as structured sets, they may all be in the same structure or they may be in different structures inside the computer.

Q. And what's your understanding of the way they are stored in the MediaWriter?

A. I believe MediaWriter tries not to keep information around, so it probably leaves information elsewhere, if at all possible. So I believe the HL7 reports are brought in and stored.

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I don't think the others are.

Q. Okay. Okay. Based on your understanding, then, the two databases that are on the outside of the MediaWriter, the second PACS and the Mitra broker, and then the HL7 report database is on the local hard drive, correct?

A. I believe so.

Q. Okay. And then the fourth separate database is the local hard drive where the images are stored.

A. That's the fourth database, yes.

Q. If you can turn to page 21 in your report, and it says:

Pre-3.0 versions of the accused products also supported structured reports.

That's at lines 11 through 13. Do you see that?

A. Yes.

Q. And do you know how the MediaWriter got structured reports prior to 3.0?

A. I would think it would be DICOM query-retrieve. That would depend on the PACS system that supported it at that time.

Q. Okay. And if you can turn to Exhibit 218,

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which you already have, which is the screen shots of the MediaWriter.

Is that what you mean by the query-retrieve methodology used by the MediaWriter to obtain structured reports?

A. This is certainly the result of that, but the actual query-retrieve would be in the code and in the design document.

Q. Okay. And is it your understanding that prior to the Version 3.0 the MediaWriter didn't have the capability of acquiring the HL7 reports and the other reports?

A. According to the user's guide, pre-3.0, it could do structured reports, and I believe it's always been able to do the HL7 reports without limitation.

Q. Okay. What makes you believe it has always been able to do the HL7 reports?

A. I guess the lack of evidence to the contrary.

Q. All right.

A. Having the reports is a necessary feature, and I don't remember that the product could never do that.

MR. HOLBROW: Can we agree that it can't

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In printer terminology, the data buffer is the temporary memory on the printer where page information is stored prior to and during the printing process.

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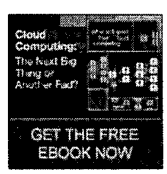

EXHIBIT 273

buffer

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(n.) A temporary storage area, usually in RAM. The purpose of most buffers is to act as a holding area, enabling the CPU to manipulate data before transferring it to a device.

Because the processes of reading and writing data to a disk are relatively slow, many programs keep track of data changes in a buffer and then copy the buffer to a disk. For example, word processors employ a buffer to keep track of changes to files. Then when you save the file, the word processor updates the disk file with the contents of the buffer. This is much more efficient than accessing the file on the disk each time you make a change to the file.

Note that because your changes are initially stored in a buffer, not on the disk, all of them will be lost if the computer fails during an editing session. For this reason, it is a good idea to save your file periodically. Most word processors automatically save files at regular intervals.

Buffers are commonly used when burning data onto a compact disc, where the data is transferred to the buffer before being written to the disc.

Another common use of buffers is for printing documents. When you enter a PRINT command, the operating system copies your document to a print buffer (a free area in memory or on a disk) from which the printer can draw characters at its own pace. This frees the computer to perform other tasks while the printer is running in the background. Print buffering is called *spooling*.

Most keyboard drivers also contain a buffer so that you can edit typing mistakes before sending your command to a program. Many operating systems, including DOS, also use a *disk buffer* to temporarily hold data that they have read from a disk. The disk buffer is really a cache.

(v.) To move data into a temporary storage area.

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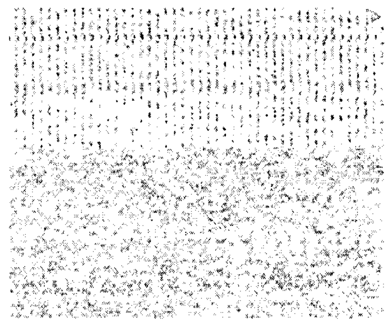

A buffer contains data that is stored for a short amount of time, typically in the computer's memory (RAM). The purpose of a buffer is to hold data right before it is used. For example, when you download an audio or video file from the Internet, it may load the first 20% of it into a buffer and then begin to play. While the clip plays back, the computer continually downloads the rest of the clip and stores it in the buffer. Because the clip is being played from the buffer, not directly from the Internet, there is less of a chance that the audio or video will stall or skip when there is network congestion.

Buffering is used to improve several other areas of computer performance as well. Most hard disks use a buffer to enable more efficient access to the data on the disk. Video cards send images to a buffer before they are displayed on the screen (known as a screen buffer). Computer programs use buffers to store data while they are running. If it were not for buffers, computers would run a lot less efficiently and we would be waiting around a lot more.

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IN THE UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

DATCARD SYSTEMS, INC., a California corporation, Plaintiff, v. PACSGEAR, INC., a California corporation, Defendant. ______________________________ AND RELATED COUNTERCLAIM	Civil Action No. SACV10-1288 DOC (VBKx) **DATCARD SYSTEMS, INC.'S REPLY IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT OF INFRINGEMENT OF U.S. PATENTS 7,783,174 AND 7,734,157** Date: February 13, 2012 Time: 8:30 a.m. Ctrm: 9D The Honorable David O. Carter

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I. INTRODUCTION

The ’174 and ’157 Patent claims are straightforward, and Pacsgear clearly infringes them. Pacsgear’s opposition seeks only to create an illusion of factual issues where none exist.

For the ’174 Patent, Pacsgear targets its efforts on the claim terms “related data” and “database.” Although Pacsgear’s discussion of these terms spans at least nine pages, the discussion essentially boils down to one fundamental legal issue of claim construction. In short, Pacsgear contends that, in light of certain embodiments in the specification, related data should be construed to mean images, and ***only*** images, and that a database means a searchable collection of images, and ***only*** images. Doc. 103 at 5, 7, 14. In Pacsgear’s view, the MediaWriter cannot infringe the claims because it stores and processes ***both*** images and textual data. *Id.* at 7–10, 16.

As DatCard explained in its opening memorandum, the Federal Circuit has repeatedly emphasized the impropriety of limiting claims to specific embodiments in the specification. Doc. 65 at 14 (citing *Linear Tech. Corp. v. ITC*, 566 F.3d 1049, 1058 (Fed. Cir. 2009)); *see also, e.g.*, *Laryngeal Mask Co. Ltd. v. Ambu A/S*, 618 F.3d 1367, 1372 (Fed. Cir. 2010). The precedent is clear: even when there is only a single embodiment described in the specification, the claims are not to be limited to that embodiment. *Linear Tech.*, 566 F.3d at 1058.

Pacsgear does not even acknowledge DatCard’s citations to the clear Federal Circuit precedent against limiting claim terms to specific embodiments, let alone explain why this is one of those rare cases falling outside this long-standing canon of claim construction. In fact, Pacsgear does not even explain why it resorts to the specification to try to limit the plain and ordinary meaning of the claim terms in the first place. Pacsgear does not contend that related data and database are technical terms with specific meanings to those skilled in the

art. Nor does it argue that these terms are ambiguous. Pacsgear certainly does not argue that the plain and ordinary meanings of related data and database exclude images. Pacsgear simply ignores the clear and unambiguous claim language, disregards the law of claim construction, and charges ahead with its own construction, plugging phrases from the specification into the claims in an effort to avoid summary judgment. As a legally erroneous brief on claim construction, Pacsgear's opposition fails to raise any genuine facts regarding its infringement of the '174 Patent.

There are clearly no triable issues of fact regarding the '157 Patent, because Pacsgear's technical experts never opined on the issue of infringement. Instead, as a last-ditch effort to avoid summary judgment, Pacsgear's opposition argues that this Court should adopt narrow constructions of (1) the word "configured" in the limitation "a computer-implemented interface configured to receive two or more requests for production of stored medical data related to the first patient"; and (2) the phrase "computer-readable medium" in the limitation "an identification specific to the computer-readable medium."

Again, Pacsgear's constructions miss the mark. The '157 Patent claims simply require a computer interface that is designed to receive multiple requests for production of stored medical data related to a patient. The MediaWriter's interface can receive any number of requests and, thus, meets the claims. Furthermore, the plain and ordinary meaning of "computer-readable medium" is any medium to which data is recorded. According to the specification, a medium can be a single CD or a collection of CDs. Both the "JobID" of MediaWriter version 4.01 and the "disc ID" of earlier versions fit the bill.

On this record, DatCard's motion should be granted.

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II. PACSGEAR HAS NOT RAISED GENUINE ISSUES OF FACT REGARDING ITS INFRINGEMENT OF THE '174 PATENT

A. Pacsgear's Construction Of "Related Data" Is Far Too Narrow

The term "related data" is a very simple, non-technical term. The words "related" and "data" are in everyone's vocabulary. In the context of the claims, the meaning of related data is unmistakable: it is, simply, data that is related to the "selected medical image data." Doc. 66-1 at 9:35–36 (reciting "a search module configured to search the database for related data based on the user selection").

Nevertheless, Pacsgear narrowly construes related data to mean images, and ***only*** images, to the exclusion of textual data, such as diagnostic reports. Doc. 103 at 14. Pacsgear's only professed rationale for construing the term related data in the first place is that Dr. Rowberg "confirmed that 'related data' had no clearly defined meaning in the medical community." Doc. 103 at 14 (citing Doc. 105-5, Pacsgear Ex. J at 106:4–107:3). Pacsgear then proclaims victory on claim construction, relying solely on Dr. Rowberg's testimony that the term related data was used in the specification to describe images. *Id.* at 14 (citing Doc. 105-5, Pacsgear Ex. J at 69:3–7, 109:13–21).

It is unclear why Pacsgear believes Dr. Rowberg's testimony helps its position in any way. On the contrary, Dr. Rowberg's testimony only confirms the fact that related data is a simple, non-technical term, with no special meaning in the art. As such, the plain and ordinary meaning controls. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (*en banc*). In any event, Dr. Rowberg's testimony (indeed, any expert's testimony) on the meaning of related data carries little weight. *See Sinorgchem Co. v. ITC*, 511 F.3d 1132, 1137 n.3 (Fed. Cir. 2007) (Without evidence that those skilled in the art would recognize a term in the specification to have an accepted meaning in the art, "testimony as to how one skilled in the art would interpret the language in the

specification is entitled to little or no weight."); *see also AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1053 (Fed. Cir. 2010) (The Federal Circuit "generally views expert testimony as less reliable than the patent and its prosecution history in determining how to read claim terms.") (internal quotation marks omitted).

DatCard does not dispute that, in the preferred embodiment, the system searches for related images. But in other embodiments, related data is discussed more broadly. Doc. 66-1 at 2:15–17 ("One embodiment of the claimed system allows for searching medical exam data that are related and placing such data on the same CD."), 4:24–26 ("The viewing program 112 also allows users to read the patient demographics and exam information [on the CD] associated with the image data.") Furthermore, even assuming that the specification disclosed nothing but images, the Federal Circuit precedent on this issue is clear: claim scope is not limited by specific embodiments in the specification, even if a disclosed embodiment is the only embodiment. *Linear Tech.*, 566 F.3d at 1058. Pacsgear does not, and cannot, dispute this precedent. Accordingly this Court should reject Pacsgear's proposed construction in favor of the clear and unambiguous language of the claims.

1. <u>The Court Should Reject Pacsgear's Eleventh Hour Attempt To Raise A New Invalidity Defense Based On The Construction Of Related Data</u>

Pacsgear raises a new validity challenge under the auspices of its opposition to Datcard's motion for summary judgment of infringement. Pacsgear baldly asserts that, because "HL7 reports and other reports are generated by different sources and retrieved from different sources than DICOM images, if related data included text reports, then the patent would fail the enablement requirement." Doc. 103 at 15. Stated more simply, Pacsgear believes that, if this Court rejects Pacsgear's claim construction limiting the

term "related data" solely to images, then the '174 Patent claims would be invalid for lack of enablement. Not only is Pacsgear's assertion unsupported by any fact, it is also contrary to law.

To support this contrived "heads-I-win, tails-you-lose" position, Pacsgear cites *Boston Scientific Corp. v. Johnson & Johnson*, 647 F.3d 1353 (Fed. Cir. 2011). *Boston Scientific* is about the issue of written description support, not enablement. In fact, that court ***expressly declined*** to address the issue of enablement. *Id.* at 1367. Because written description and enablement are separate issues, *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1340 (Fed. Cir. 2010) (*en banc*), it is unclear why Pacsgear believes *Boston Scientific* is even relevant. It is not.

In addition, contrary to Pacsgear's assertion, "[e]nablement does not require the inventor to foresee every means of implementing an invention at pains of losing [the] patent franchise. . . . Such narrow patent rights would rapidly become worthless as new modes of practicing the invention developed, and the inventor would lose the benefit of the patent bargain." *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1071 (Fed. Cir. 2005). Thus, DatCard was not required to foresee and disclose Pacsgear's specific implementation of DatCard's invention in order to obtain valid claims broad enough to cover that implementation.

In any event, Pacsgear's argument is soundly rebutted by clear Federal Circuit precedent ***against*** limiting the claims to the embodiments in the specification. *Linear Tech.*, 566 F.3d at 1058. Pacsgear cannot make this precedent disappear by ignoring it. The Court thus should reject Pacsgear's invitation to create a triable issue, where no issue exists.

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2. <u>The Prosecution History Does Not Support Pacsgear's Construction Of Related Data</u>

Citing a declaration filed by inventor Ken Wright during prosecution of the '164 Patent (the grandparent of the '174 Patent), Pacsgear lastly contends that the "prosecution history confirms that the scope of the invention is limited to selected images and related images." Doc. 103 at 15 (citing Doc. 106-1, Pacsgear Ex. 5 ¶ 3.)

Pacsgear neglects to mention that, in this declaration, Mr. Wright discussed a different patent, with different claims, and with different claim language. *See generally* Doc. 106-1, Pacsgear Ex. 5. Moreover, Pacsgear also fails to acknowledge that Mr. Wright did not even mention "the invention," much less discuss the scope of the invention. He simply discussed the specification generally. *Id.* ¶ 3 ("The '795 Application discloses . . .")

It is undisputed that the specification's preferred embodiment includes a search for related images. Mr. Wright confirmed this and said nothing more. Pacsgear has not provided even one viable basis for limiting the claims to the precise scope of the preferred embodiment. Accordingly, Pacsgear's construction of related data fails as a matter of law.

B. <u>Pacsgear's Incredibly Narrow Construction Of "Database" Bears Little Resemblance To The Actual Claims</u>

Pacsgear espouses a complicated construction of "database" that Pacsgear purports to be "drawn from the context in which it is used in the claims," namely: an "electronic collection of image data stored in a way to allow for easy search and retrieval following the request of a user." Doc. 103 at 5–6. This Court should make no mistake: this construction is not "drawn from" the claims; it entirely rewrites the claims to remove the "related data" language that is so problematic for Pacsgear.

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Pacsgear explains the "logic" of its construction as follows: "Based on the claim limitations alone we know that [the second and fourth limitations of claim 1] are referring to the same database and the database (i) stores image data [limitation 2] and (ii) is searchable based on the user's selection [limitation 4]." Doc. 103 at 6. But this logic is incomplete because it focuses solely on the words "image data" in the second limitation and ignores the words "related data" in the fourth limitation.

The second limitation of claim 1 recites "a database configured to store medical image data . . . ." Doc. 66-1 at 9:30–31. The fourth limitation actually recites "a search module configured to automatically search the database ***for related data*** based on the user selection [of selected medical image data]." *Id.* at 9:33–36 (emphasis added). Thus, the database plainly includes both image data and related data. Accordingly, in order for Pacsgear's definition of database to be truly "drawn from" the claims, the definition would need to be amended to read: "an electronic collection of medical image data ***and related data*** stored in a way to allow for a search ***of the related data*** based on a user selection of the medical image data."

Pacsgear's construction bears little resemblance to the actual claim language. Most glaringly, Pacsgear's construction fails to acknowledge that the database stores ***both*** medical image data and related data.

1. <u>This Court Should Reject Pacsgear's Attempt To Limit Database To A Structure That Only Stores Images</u>

Pacsgear never explains why it feels compelled to piece together over twenty words in order to define a simple word like database. But Pacsgear's motives are plain: Pacsgear wants a second shot at limiting the claims to images, and ***only*** images, to the exclusion of any other kind of related data including textual data. *See* Doc. 103 at 7 (suggesting that Pacsgear's construction of database only encompasses images and not text).

As set forth in DatCard's opening memorandum and emphasized above, this Court should reject Pacsgear's construction because it improperly limits the claims to embodiments in the specification. Doc. 65 at 6.

2. <u>Pacsgear's Criticisms Of DatCard's Plain And Ordinary Meaning of Database Are Unfounded</u>

As DatCard has previously explained, database is an ordinary word familiar to both skilled artisans and laypeople alike. Doc. 65 at 5. In the claims, database is used in its ordinary sense. *Id.* Similarly, in the specification, database is generically used to describe computer modules that store data, including medical image data, related data, and audit records. *Id.* (citing Doc. 66-1 at 3:65–4:2, 6:1–15, 6:53–59).

Pacsgear repeatedly criticizes DatCard for referring to a dictionary to confirm the plain and ordinary meaning of the term database. Doc. 103 at 5–6. This criticism is unfounded. The Federal Circuit has expressly approved of the use of dictionaries to ascertain ordinary meaning. *See Cordis Corp. v. Boston Sci. Corp.*, 658 F.3d 1347, 1356 (Fed. Cir. 2011) (beginning construction by referring to a dictionary definition to ascertain ordinary meaning of a claim term); *Verizon Servs. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1304 (Fed. Cir. 2007) (when the specification does not define a term, it is proper to consult a dictionary to determine its ordinary meaning).

DatCard's dictionary definition of database simply confirms what everyone already understands it to mean in light of the claims and specification: a structured set of data held in a computer.

3. <u>Pacsgear's Bald Attorney Arguments Do Not Raise Genuine Issues of Fact</u>

DatCard has provided ample evidence to prove that the MediaWriter includes a database. Doc. 65 at 7 (citing Doc. 83, Ex. 2 at 25:20–26:24; Doc. 83, Ex. 6 at 11; Doc. 83, Ex. 7 at PG009437; Doc. 83, Ex. 8 at PG015479;

Doc. 85, Ex. 23 (Rowberg Decl.) at 55–56.) Even Pacsgear's own specifications describe the MediaWriter's local drive as a "database." Doc. 83, Ex. 7 at PG009437; Doc. 83, Ex. 8 at PG015479. Pacsgear tries to dismiss this overwhelming documentary evidence of infringement in a footnote, stating that this "extrinsic evidence . . . has no bearing on claim construction/related analysis." Doc. 103 at 9 n.9. DatCard is not using Pacsgear's documents for claim construction; DatCard is using them to prove infringement. If Pacsgear is seriously contending that extrinsic evidence has no bearing on infringement, Pacsgear is sorely mistaken.

In opposition, Pacsgear does not cite any meaningful evidence demonstrating that the MediaWriter lacks a database. Instead, Pacsgear throws out a handful of factually unsupported attorney arguments about the structure of the MediaWriter's local drive in the hopes that something sticks enough to raise a genuine issue of fact. Doc. 103 at 8–9. For example, Pacsgear argues that a "'buffer' is not a database," *id.* at 8:23; "a 'file system' . . . does not store images and is not a database," *id.* at 9:7–8; and a "hard drive is not a database," *id.* at 9:20. Pacsgear's bald argument simply cannot defeat DatCard's properly supported motion for summary judgment. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 257, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986); *Davis v. Pioneer Credit Recovery, Inc.*, No. CV 11–1963–JEM, 2012 WL 10376, at *6 (C.D. Cal. Jan. 3, 2012) (a "nonmoving party must present affirmative evidence in order to defeat a properly supported motion for summary judgment") (internal citations and quotation marks omitted); *accord Glaverbel Societe Anonyme v. Northlake Mktg. & Supply, Inc.*, 45 F.3d 1550, 1562 (Fed. Cir. 1995) ("Argument is not evidence upon which to base a denial of summary judgment.") Here, the evidentiary record is unequivocal: Pacsgear admits that the MediaWriter has a database. Doc. 83, Ex. 7 at PG009437 ("Images received . . . shall be stored in the local database"); Doc. 83, Ex. 8 at PG015479 (same).

Perhaps recognizing the total want of evidence to support its opposition, Pacsgear attempts to rely upon testimony by Dr. Rowberg to bolster its arguments. Pacsgear states: "Dr. Rowberg also confirms that the buffer location on the hard drive is not the same 'database' as the folder storing HL7 reports." Doc. 103 at 9:11–12 (citing Doc. 105-5, Pacsgear Ex. J at 172:2–11). Dr. Rowberg confirmed no such thing. In this portion of Dr. Rowberg's deposition, Pacsgear's counsel asked Dr. Rowberg to identify "examples of how the MediaWriter would infringe if the court concludes that the database has to be the same database in both the second and fourth limitations." Supp'l Stewart Decl., Ex. 30 at 169:1–4. Because a MediaWriter is capable of interacting with several different databases, including its own local drive, Dr. Rowberg discussed four viable infringement theories. *Id.* at 169:5–172:11. In the specific colloquy quoted by Pacsgear, Dr. Rowberg was not testifying that a HL7 report database is different than the local hard drive where images are stored. He was testifying that each of these is a "database" that falls within the scope of the claims. Dr. Rowberg specifically disagreed with Pacsgear's repeated efforts to characterize them as "distinct" or "separate" databases. *Id.* at 171:13–16 ("Maybe 'distinct database' isn't the right term because the information sources might all be stored in the same database, so it might not be a distinct database."). Thus, Dr. Rowberg's testimony cannot salvage Pacsgear's failure of evidence.

In yet another attempt at misdirection, Pacsgear also suggests that the MediaWriter might not infringe the '174 Patent because, according to Pacsgear's attorney, the '174 Patent specification allegedly excludes buffers from the scope of the claim term "database." Doc. 103 at 8:6–8 ("The '174 Patent describes a buffer system (like the one used by the MediaWriter) and not only doesn't identify it as a database but because it is just a buffer states that the images are not even 'stored' through this process . . . .") As its sole support for

this theory, Pacsgear quotes a passage from the ’174 Patent specification that does not so much as mention a “buffer.” *Id.* at 8:9–11. In fact, the ’174 Patent does not use the word buffer even once. Pacsgear simply cannot rely upon unsupported attorney argument about the scope of the specification to raise a genuine issue of fact. *See Glaverbel*, 45 F.3d at 1562 (attorney argument regarding technical issues is not affirmative evidence raising an issue of fact).

Pacsgear’s only other basis for arguing that the MediaWriter lacks a database is its contention that the “MediaWriter cannot search its hard drive for images.” Doc. 103 at 9:3–4. Even assuming that Pacsgear is correct, this argument is irrelevant because claim 1 does not recite a search module that searches for related ***images***. Claim 1 recites a search module that searches for related ***data***, more generally. And the MediaWriter is clearly configured to search its local drive for related data, including “HL7” reports and other diagnostic reports. Doc. 83, Ex. 2 at 34:8–35:3, 38:25–39:12; *see also* Doc. 85, Ex. 23 (Rowberg Decl.) at 58–59.

Thus, there are no issues of fact to resolve: based on the evidentiary record, Pacsgear plainly meets the claims.

C. <u>Pacsgear’s Construction Of Automatically Is Legally Improper Because It Ignores The Open-Ended Preamble “Comprising”</u>

As expected, Pacsgear perseveres in arguing a narrow construction of “automatically” in the opposition. Doc. 103 at 11–12. Amazingly, however, Pacsgear offers five different possibilities for the Court to consider: (1) “without asking for user direction,” Doc. 104 at 12:3; (2) “without prompting for user selection,” *id.* at 12:3–4; (3) “without volition,” Doc. 103 at 11:23; (4) without “significant user intervention,” *id.* at 12:22–23; and (5) “acting or operating in a manner essentially independent of external influence or control,” *id.* at 11:23. Apparently, Pacsgear must hope that, by offering this Court a host of possible constructions, Pacsgear will raise enough factual issues to help it defeat

DatCard's motion for summary judgment. Pacsgear is wrong. Claim construction is an issue of law for the Court to resolve. *Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357, 1370 (Fed. Cir. 2010).

It is a fundamental tenet of claim construction that the transitional term "comprising" is open-ended and does not exclude additional, unrecited elements, such as the acts of a user. *CollegeNet, Inc. v. ApplyYourself, Inc.*, 418 F.3d 1225, 1235 (Fed. Cir. 2005); *Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1371–1372 (Fed. Cir. 2005) ("The word 'comprising' transitioning from the preamble to the body signals that the entire claim is presumptively open-ended. . . . The addition of elements not recited in the claim cannot defeat infringement.").

Claim 1 of the '174 Patent uses the open-ended transitional word comprising in the preamble. Doc. 66-1 at 9:25 (a "system comprising"). Nevertheless, Pacsgear contends that the MediaWriter does not "automatically" search the MediaWriter database because users must take actions like "positioning the [mouse] cursor" and "click[ing] the computer's mouse" before initiating a search. Doc. 103 at 13. Pacsgear's proposed constructions, which improperly exclude unrecited user actions, are therefore incorrect as a matter of law. *See CollegeNet*, 418 F.3d at 1235 (The "use of 'comprising' suggests that additional, unrecited elements are not excluded. Such elements could include human actions to expressly initiate the automatic [computer functions], or to interrupt such functions.") Pacsgear does not, and cannot, distinguish this long-standing rule enunciated in *CollegeNet*.

1. <u>The Court Should Reject Pacsgear's Attempt To Raise Yet Another New Invalidity Defense Based On The Construction Of Automatically</u>

Once again, Pacsgear uses the auspices of its opposition to an infringement motion to raise an entirely new validity challenge. Pacsgear

contends — for the first time in this litigation — that if DatCard's construction prevails, then the claims would be invalid for anticipation by "Heartlab's DICOMView System." Doc. 103 at 12.

It is absolutely bewildering that Pacsgear attempts to raise this eleventh hour validity challenge in an opposition brief to a motion for summary judgment of infringement. Pacsgear has represented its bases for arguing invalidity, and ***not once*** has Pacsgear contended that Heartlab anticipates the '174 Patent. Supp'l Stewart Decl., Exs. 22, 24, 25, 26; Doc. 105-1, Pacsgear Ex. A at 15, 16, 30. Discovery has long since closed and Pacsgear is bound by its interrogatory answers and disclosures. Pacsgear is simply not permitted to present this previously undisclosed defense. *See Spellbound Dev. Group, Inc. v. Pac. Handy Cutter*, No. SACV 09-00951, 2011 WL 5554312, at *5–6 (C.D. Cal. Nov. 14, 2011) (Carter, J.) (limiting party to infringement theories disclosed in interrogatory responses); *Brilliant Instruments, Inc. v. GuideTech, Inc.*, No. C 09-5517, 2011 WL 900369, at *2 (N.D. Cal. Mar. 15, 2011) (limiting invalidity to prior art disclosed in invalidity contentions).

Even if Pacsgear were entitled to raise this argument — and Pacsgear is clearly not entitled to do so — it is simply irrelevant to the issue of claim construction in this summary judgment motion. *See Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1384 (Fed. Cir. 2001) (holding that a court is not obligated to construe claims to preserve validity over newly discovered prior art).

In any event, Pacsgear's argument is completely unsupported. As the Court can see for itself, Pacsgear simply ignores most of the claim limitations, and it takes extraordinary liberties with the few claim limitations that it does acknowledge. Doc. 103 at 12. Then, Pacsgear squeezes its entire anticipation "analysis" into just over ***four lines*** of text. *Id.* at 103 at 12:11–15. Unsubstantiated attorney argument regarding a technical issue like anticipation

does not raise a genuine issue of fact. *See Glaverbel*, 45 F.3d at 1562 ("There must be sufficient substance, other than attorney argument, to show that the issue requires trial.") Simply put, this attorney argument is not a credible basis for invalidity and it does not inform the proper construction of the term "automatically"; it is nothing more than a diversionary tactic.

2. <u>The MediaWriter Clearly Meets The Claims</u>

There are no issues of fact to resolve. Here, the facts are clear: once a user clicks the "Confirm" button to confirm a selection of medical image data, the MediaWriter will then search for related data without asking for user direction, without prompting for user selection, without volition, without any user intervention, and completely independent of external influence or control. Doc. 66-3 at PG006766; Doc. 66-4 at PG006804; Doc. 83, Ex. 2 at 34:8–35:3, 38:25–39:12; *see* Doc. 103 at 13. The MediaWriter clearly meets the claims.

D. <u>Pacsgear's Has Not Raised A Genuine Issue Of Fact Regarding Contributory Infringement</u>

Pacsgear does not deny that MediaWriters have a web client. Doc. 103 at 11. Instead, as predicted, Pacsgear argues that MediaWriters have a substantial noninfringing use, because some customers use MediaWriters without turning on the web client. *Id.* As DatCard explained in its opening memorandum, this theory has been expressly rejected by the Federal Circuit. Whether a customer actually turns on the web client is "relevant to the extent of direct infringement, but ***[it] does not establish substantial noninfringing uses***." *Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1331 (Fed. Cir. 2010) (emphasis added); *see also i4i LP v. Microsoft Corp.*, 598 F.3d 831, 850–51 (Fed. Cir. 2010); *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1320–21 (Fed. Cir. 2009); *Ricoh Co., Ltd. v. Quanta Computer Inc.*, 550 F.3d 1325, 1337–39 (Fed. Cir. 2008).

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Pacsgear's citation of *C.R. Bard, Inc. v. Advanced Cardiovascular Systems, Inc.*, 911 F.2d 670 (Fed. Cir. 1990) is unavailing. That case involved the issue of contributory infringement of a claim to a therapeutic method. The defendant sold a special catheter that physicians could use in both infringing and noninfringing methods. The Federal Circuit concluded that "it remains true that on this record a reasonable jury could find that, pursuant to the procedure described in the first of the fact patterns (a noninfringing procedure), there are substantial noninfringing uses for the . . . catheter." *C.R. Bard*, 911 F.2d at 674. *C.R. Bard*, unlike *Fujitsu*, did not involve a device that has a feature that was specially designed to infringe but could theoretically be turned off.

The facts on this record are quite different from those in *C.R. Bard*. Here, DatCard asserts that Pacsgear's customers are directly infringing system claims in the '174 Patent when the customers use a MediaWriter with a multiple browsing terminals, according to Pacsgear's instructions. Some customers turn on the MediaWriter's web client feature that enables a connection to the browsing terminals, and some customers do not. But the MediaWriter includes everything that the customers need to infringe the claim. On these facts, the precedent of *Fujitsu* is clear: the customers' ability to turn the web client on or off does not establish substantial noninfringing uses, as a matter of law. *See* 620 F.3d at 1331. Again, Pacsgear cannot make Federal Circuit precedent disappear by ignoring it.

In passing, Pacsgear also contends that "the fourth contributory infringement factor is not satisfied as a plurality of browsing terminals is not a material part of the invention." Doc. 103 at 11:16–18. Pacsgear's analysis is wrong. The issue is ***not*** whether the customers' browsing terminals are a material part of the invention. The issue is whether Pacsgear's MediaWriter is a material part of the invention. *See Fujitsu*, 620 F.3d at 1326. And, clearly, it is. As explained in DatCard's opening memorandum, MediaWriter satisfies every

element of claim 1 except for the plurality of browsing terminals. Doc. 65 at 3–15; *see also* Doc. 85, Ex. 23 (Rowberg Decl.) at 62. Furthermore, the MediaWriter includes special software to allow connection to additional browsing terminals. *Id.*

On this record, Pacsgear is contributing to its customers' infringement. Pacsgear has not raised any issues of fact to dispute this. Accordingly, DatCard requests that this Court grant DatCard's motion for summary judgment as to the '174 Patent.

III. THE UNDISPUTED EVIDENCE PROVES THAT MEDIAWRITER INFRINGES CLAIMS 7 AND 12 OF THE '157 PATENT

A. MediaWriter Versions 4.0 And Earlier Plainly Infringe Claim 7

In its opposition brief, Pacsgear divides claim 7 into three limitations. *See* Doc. 103 at 16:23–17:7. Pacsgear does not dispute that all versions of the MediaWriter satisfy the second limitation. In addition, Pacsgear concedes that its "disc ID" feature satisfies the third limitation of the claim. *Id.* at 19 n.13. It is undisputed that the "disc ID" feature was present in Version 4.0 of MediaWriter and all earlier versions. *See* Doc. 66-3 at PG006785; Doc. 66-4 at PG006827; *see also* Doc. 84, Ex. 22 (Goldberg Decl.) at 40–45 (discussing the source code for the "disc ID" feature). Thus, the only dispute regarding Versions 4.0 and earlier is whether they satisfy the first limitation of claim 7. They clearly do.

The first limitation reads: "a computer-implemented interface ***configured*** to receive two or more requests for production of stored medical data related to the first patient." Doc. 66-20 at 10:17–19 (emphasis added). Pacsgear asserts that this limitation requires the user to make "two requests for production relating to the same patient." Doc. 103 at 17:19; s*ee also id.* at 17:21–22 ("the claim requires the user to make two separate requests"). Pacsgear's claim construction is wrong as a matter of law.

The disputed claim limitation says nothing about what a "user" must do. To the contrary, the claim is directed to an apparatus, not a method of using an apparatus. In particular, the claim is directed to a "system for generating a portable computer-readable medium." Doc. 66-20 at 10:12–13. That system must have the three structural features listed in claim 7. Of particular importance here, the system must have a computer interface that is "***configured*** to receive two or more requests for production of stored medical data related to the first patient." *Id.* at 10:17–19 (emphasis added). That is, the computer interface must have structural components that enable it to receive two or more requests for production of stored medical data related to the first patient.

The MediaWriter plainly meets this requirement. The MediaWriter has a computer interface that is specifically designed to receive requests for production of stored medical data related to a patient. The user merely types the patient's name into the computer interface. *See* Doc. 66-3 at PG006755 (MediaWriter includes a "simple user interface that can be installed on any PC"); *id.* at PG006767 (picturing the interface); Doc. 85, Ex. 23 (Rowberg Decl.) at 81. There is no limit to the number of times a user may enter the same patient's name, and Pacsgear has pointed to no evidence of any such limitation. Thus, the MediaWriter is "configured" to receive two or more requests for production of stored medical data related to the first patient.

B. <u>MediaWriter Version 4.01 Also Infringes Claim 7</u>

When Pacsgear released MediaWriter Version 4.01, it deleted the "disc ID" feature, but retained the "Job ID" feature. Doc. 103 at 19:17–19. Pacsgear asserts that the use of the "Job ID" feature instead of the "disc ID" feature avoids infringement. In particular, Pacsgear contends that the Job ID number is not "an identification specific to the computer-readable medium," as required by claim 7. *See* Doc. 103 at 17–19. Pacsgear is wrong and its error is entirely one of claim construction.

The claim construction dispute between the parties is actually quite simple. DatCard contends that a "computer-readable medium" is any medium to which data is recorded. It can be a single CD if the job is small enough, or it can be a collection of CDs if the size of the job requires two or more CDs. Pacsgear contends that the "computer-readable medium" must be a single CD. Doc. 103 at 18–19.

The specification explicitly supports DatCard's construction. The specification states: "Digital portable recording medium comprises CDs and DVDs." Doc. 66-20 at 3:30–31. The plural form "CDs" and "DVDs" is clearly used. This indicates to any reasonable reader that the "medium" on which information will be recorded by the patented invention may be more than a single CD or DVD. Pacsgear has ignored this express disclosure.

The portion of the specification on which Pacsgear relies does not undercut this disclosure. *See* Doc. 103 at 18:19–24 (quoting an unspecified portion of the specification). The quoted text merely assumes for the sake of simplicity that a job will consist of a single CD. *See id*. It does not suggest in any way that the term computer-readable medium is limited to be a single CD. In contrast, the portion of the specification on which DatCard relies explicitly declares that a "computer-readable medium" may include multiple CDs or DVDs.

Pacsgear also argues that the word "medium" is singular, and that the claimed "computer-readable medium" therefore must be a single CD. This argument is fatuous. The very first "computer readable medium" was a collection of punchcards. No one could rationally deny that the medium was the entire set of punchcards. A single punchcard is of little value because it is too small to store even a simple computer program. Similarly, the movie *Gone With The Wind* is recorded on a projector-readable medium, even though it is stored on multiple reels of film. And the *Encyclopedia Brittanica* is printed on

a human-readable medium even though it is bound in multiple volumes, each of which has multiple pages.

As these simple examples illustrate, the word medium ordinarily refers to the ***type*** of information storage device, not the ***quantity***. Thus, Pacsgear could perhaps avoid literal infringement if it chose to store part of its information on CDs and part of its information on punchcards, assigning the same Job ID number to both. But it has not. It has chosen the same medium disclosed in the preferred embodiment of the patent — CDs. It has relied on this medium, and this medium alone, and Pacsgear provides an identification number for each set of CDs produced. Pacsgear thus meets the claim limitation calling for "an identification specific to the computer-readable medium."

C. The Dispute Over The Meaning Of The Word "Specific" Is Not Relevant To Any Issue Remaining Before This Court

Pacsgear devotes one paragraph of its brief to arguing that the claim term "specific" should be construed to mean "unique." Doc. 103 at 18:12–15. This claim construction issue, however, relates to a dispute that is no longer before this Court.

During discovery, Pacsgear had argued that its "disc ID" feature did not satisfy the third limitation of claim 7 because multiple copies of the same identical disc will bear the same "disc ID" number. Per Pacsgear, each copy of the same disc needed to have its own unique identification number in order to meet the claim's requirement for "an identification specific to a computer-readable medium." *See* Supp'l Stewart Decl., Ex. 23 at 13:26–14:3. In response, DatCard argued that "[s]pecific does not mean that each ***duplicate copy*** of the same disc has a unique number." Doc. 65 at 22:14–15 (emphasis in original).

Pacsgear, however, is no longer arguing that the ability to make duplicate copies of the same disc with the same "disc ID" number avoids infringement. In

fact, Pacsgear concedes that the "disc ID" feature satisfies the third limitation of claim 7. Doc. 103 at 19 n.13. Accordingly, the meaning of the word "specific" is no longer material to any issue remaining before this Court.

D. <u>MediaWriter Also Infringes Claim 12</u>

Pacsgear presents no separate argument against infringement of claim 12 of the '157 Patent, which depends from claim 7. *See* Doc. 103 at 20:1–2. Accordingly, for all the reasons just explained, Pacsgear infringes claim 12.

IV. CONCLUSION

Pacsgear's opposition is a brief on claim construction that inexplicably ignores the law at every turn. It is supported only by attorney argument and a few purported "admissions" taken wholly out of context. Accordingly, Pacsgear has failed to present any triable issue of fact. On this record, infringement is clear, and DatCard respectfully requests that the Court grant DatCard's motion for summary judgment in its entirety.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

DATCARD SYSTEMS, INC., a California corporation, Plaintiff, vs. PACSGEAR, INC., a California corporation, Defendant.	) Case No. SACV 10-1288 DOC (VBKx) (PER PROTECTIVE ORDER SECTION 11 THIS TRANSCRIPT HAS A TEMPORARY "CONFIDENTIAL - OUTSIDE COUNSEL ONLY" DESIGNATION FOR A PERIOD OF 14 DAYS AFTER THE DEPOSITION IS RECEIVED.)
COMPLETE CAPTION ON NEXT PAGE.	

DEPOSITION OF

ALAN H. ROWBERG, M.D.

LOS ANGELES, CALIFORNIA

DECEMBER 16, 2011

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REPORTED BY: SUSAN M. PATTERSON, CSR NO. 2448
FILE NO.: A50BB63

EXHIBIT 30

Q. Okay. Any other examples of how the MediaWriter would infringe if the court concludes that the database has to be the same database in both the second and fourth limitations? 16:00:21 16:00:26 16:00:30 16:00:33

A. I could conceive that the MediaWriter would go out and get the Mitra broker reports and store them in the local database. And I don't know whether it does that or not, but that might be another possible way to infringe. 16:00:44 16:00:47 16:00:54 16:00:57 16:01:00

Q. And then go back and search the Mitra broker? 16:01:02 16:01:05

A. Well, go back and search the local database and find them in there. 16:01:06 16:01:08

Q. Okay. Any other examples? 16:01:10

A. Well, images from the second PACS system could be stored in that same database and then searched. 16:01:20 16:01:23 16:01:27

Q. Which database? 16:01:27

A. The one from limitation number 2. That database could conceivably hold all four types of data. 16:01:30 16:01:33 16:01:39

Q. The PACS database? 16:01:40

A. The MediaWriter database of limitation 2. 16:01:42

Q. Okay. Do you know that is the case? 16:01:47

A. I do not. 16:01:51

EXHIBIT 30

Q. Okay. So looking at the next claim, we 16:01:51
can go to claim 15, the term "database" appears in 16:02:36
limitation 2 and in limitation 4. 16:02:51
A. (Reviews document.) 16:03:09
Q. Do you see that? 16:03:10
A. Yes. 16:03:11
Q. Okay. And in terms of what databases in 16:03:12
the MediaWriter satisfy that limitation, would it be 16:03:22
the same for distinct databases that we discussed 16:03:25
earlier: the local hard drive where the images are 16:03:30
stored, the database where the HL7 reports are 16:03:34
stored, the Mitra broker, and a second PACS? 16:03:42
A. I believe that claim 15 is a restatement 16:03:48
of Claim 9 with a modification at the end, so all of 16:03:51
the words are the same and all of the conclusions 16:03:55
are the same. 16:04:02
Q. Okay. And I just want to do it for this 16:04:03
claim. So is it accurate to say that the four 16:04:08
distinct databases that are associated with the 16:04:12
MediaWriter, in your opinion, that satisfy the 16:04:12
"database" term in claim 15 are the local hard drive 16:04:14
where images are temporarily stored, the HL7 16:04:18
database where the HL7 reports are stored, a second 16:04:24
PACS, and a Mitra broker? 16:04:28
A. And depending on what assumptions we make 16:04:33

about the database in claim 2 and whether it has to be inside the MediaWriter. You asked about two different cases. So the PACS and the Mitra broker images might conceivably be inside the MediaWriter as well as outside. 16:04:38 16:04:44 16:04:48 16:04:54 16:04:58

Q. Okay. So the four databases are the local hard drive where the images are stored, the HL7 database where the HL7 reports are stored, and the second PACS, and the Mitra broker? 16:04:59 16:05:07 16:05:11 16:05:16

A. Whether they are inside or outside. 16:05:18

Q. Whether they are inside or outside, those are the four distinct databases? 16:05:21 16:05:23

A. Maybe "distinct databases" isn't the right term because the information sources might all be stored in the same database, so it might not be a distinct database. If we define "database" as structured sets, they may all be in the same structure or they may be in different structures inside the computer. 16:05:30 16:05:34 16:05:38 16:05:41 16:05:50 16:05:52 16:05:56

Q. And what's your understanding of the way they are stored in the MediaWriter? 16:05:57 16:05:59

A. I believe MediaWriter tries not to keep information around, so it probably leaves information elsewhere, if at all possible. So I believe the HL7 reports are brought in and stored. 16:06:03 16:06:05 16:06:08 16:06:14

EXHIBIT 30

I don't think the others are.
Q. Okay. Okay. Based on your understanding, then, the two databases that are on the outside of the MediaWriter, the second PACS and the Mitra broker, and then the HL7 report database is on the local hard drive, correct?
A. I believe so.
Q. Okay. And then the fourth separate database is the local hard drive where the images are stored.
A. That's the fourth database, yes.
Q. If you can turn to page 21 in your report, and it says:

> Pre-3.0 versions of the accused products also supported structured reports.

That's at lines 11 through 13. Do you see that?
A. Yes.
Q. And do you know how the MediaWriter got structured reports prior to 3.0?
A. I would think it would be DICOM query-retrieve. That would depend on the PACS system that supported it at that time.
Q. Okay. And if you can turn to Exhibit 218,

16:06:17 16:06:19 16:06:32 16:06:44 16:06:48 16:06:52 16:06:54 16:06:59 16:07:03 16:07:07 16:07:10 16:07:20 16:07:23 16:08:03 16:08:07 16:08:09 16:08:17 16:08:20 16:08:44 16:08:47 16:08:52 16:08:56

EXHIBIT 30

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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
SOUTHERN DIVISION

DATCARD SYSTEMS, INC., a California corporation Plaintiff, v. PACSGEAR, INC., a California corporation Defendant.	Case No. SACV 10-1288 DOC (VBKx) **PACSGEAR'S REPLY MEMORANDUM IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT OF THE "SEARCH/BURN" PATENTS**
PACSGEAR, INC., a California corporation, Counter-Claimant, v. DATCARD SYSTEMS, INC., a California corporation, Counter-Defendant.	Courtroom of Judge Carter Discovery Cut-Off: Dec. 23, 2011 Trial Date: April 17, 2012

Pacsgear submits the following Reply Memorandum In Support of its Motion for Summary Judgment of Infringement of the '164, '174 and '597 Patents[1].

I. ALL SOURCES PROVE THAT RELATED DATA IS CONFINED TO IMAGE DATA IN DICOM FORMAT

DatCard contends that related medical image data ('164) related medical data ('597) and related data ('174) all include text reports. It ignores the claim language, specification, file history, the testimony of both sides' experts and DatCard inventor-founder-CEO-30(b)(6) witness Ken Wright.

A. Intrinsic and Extrinsic Evidence Support PacsGear's Claim Construction

Claim Language:

'164 Patent Claim 9 – limitation 5 – "related medical image data, recorded in the standard medical imaging format". DatCard does not dispute that images stored in the standard medical imaging format (i.e., DICOM) necessarily exclude text reports.

Specification:

Q. Is there anything in the specification that teaches that "related data" can mean anything other than images? And if there is, please find it.

A. I don't know of a citation that teaches that.

Q. And you are more than welcome to look. You're confident you won't find anything?

A. I believe I tried this morning and couldn't find that." (Ex. J, Rowberg Dep. 109:13-21)

File History:

In his declaration filed in July 2009, during the prosecution of the '164 Patent, inventor Ken Wright declared:

[1] Pacsgear incorporates by reference its Opposition to DatCard's Motion for Summary Judgment of Non-Infringement of the '174 Patent and related exhibits.

"The application server allows users to select medical images of interest and search for additional medical images that are related to the selected images. The selected and related medical images can then be recorded onto a portable data storage medium, such as a compact disc, using the standard medical imaging format."

Ex. 5, ¶3. No mention of text reports.

Extrinsic Evidence:

Q. "So one skilled in the art seeing "image data" would think that it only meant---it only referred to images to the exclusion of other things, correct?

A. Yes."

(Ex. J, Rowberg Dep. 123:8-12)

Q. Okay. So in this claim, anyway, the term "related medical image data" necessarily refers to images?

A. It seems to.

(Exhibit J - Rowberg 62:2-5)

Ken Wright testified that eFilm viewing software used in the system could only view images –not text reports. (Ex.1, Wright Dep. 156:7-9).

B. DatCard's Support for Inclusion of Text Reports Was Rejected By Its Own Expert

DatCard relies on only two sentences from the specification to support its position that "related data" includes text reports: 1) "[o]ne embodiment of the claimed system allows for searching medical exam data that are related and placing such data on the same CD" and 2) The specification discloses a viewing program that "allows users to read the patient demographics and exam information associated with the image data" stored on the CD. (DC Opp. Brief p. 5) It contends the terms "medical exam data" and "exam information" mean written reports

Dr. Rowberg initially testified in support of that position by calling out the first sentence . On further questioning, Rowberg admitted that medical exam data actually only referred to images throughout the specification. (Ex. J, pp. 54:21-60:18)

The second sentence describes how the viewing software allows "users to read the…."exam information" associated with the image data." In the context of that portion of the specification, exam information refers to the identifying information associated with the images in DICOM format (See, Horii Report Ex., p.25, fn. 6) it does not have anything to do with a separate text report.

C. DatCard's Focus On Individual Words In A Vacuum Causes Errors In Claim Construction.

In both examples in B above, DatCard looks at individual words and phrases, divorced from the context in which they appear. Thus, it argues that the word "related" is perfectly understandable to the ordinary reader, while ignoring the fact that related medical image data must be storable on a DICOM database and be copied in DICOM format onto a CD. ('164 patent, limitations 3-5). This tunnel vision approach is contrary to law:

"Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) "[W]hen a patentee uses a claim term throughout the entire patent specification, in a manner consistent with only a single meaning, he has defined that term `by implication.'" *Astrazeneca LP v. Apotex, Inc.* 633 F.3d 1042, 1052 (Fed. Cir. 2010).

Read properly, "related medical image data" and its spin-offs "related medical data," "related data" and "additional data" all must be image data in DICOM format. They cannot include text data. As Rowberg ultimately agreed using tunnel vision results in nonsense constructions.

II. MEANING OF "DATABASE" DETERMINED BY THE CLAIMS AND THE SPECIFICATION IS CONFINED TO A SEARCHABLE DATABASE CARRYING IMAGES IN DICOM FORMAT

A. DatCard's Dictionary Definition Is Unhelpful

DatCard found the broadest dictionary definition of "database" and urges the Court to adopt it based on the theory that "Everyone understands what a database is." (Brief p. 9). Extrinsic dictionary definitions, particularly from non-technical dictionaries, are to be used with caution. Relying on a dictionary definition is worse than DatCard's tunnel vision problem, because the dictionary has no connection with the patent at all.

B. A Database In The '164, '597[2] and '174 Patents Can Only Store Image Data

The second limitation of the '174 patent - the first limitation to use "database" - states:

[2] "a database configured to store medical image data generated by one or more imaging modalities"

The next time database appears in the claim is in the fourth limitation, which states:

[4]" a search module configured to automatically search the database for related data based on the selection of a user".

"Because it has defined "database" and then says "the database," I think it's referring back to the same one. So I would think it would be the same." (Ex. J - Opp., Rowberg Dep. 40:1-15).The databases identified in the specification that store medical image data, only store images. (e.g., Ex. 265, See Fig. 1 - "Image

[2] The '597 Patent calls for searching two databases, one for selected data and the second for related data.

Server Database). Inventor Ken Wright testified that a PACS database only stores images. . (Ex. I – Opp., Wright Dep., pp. 148-149).

C. DatCard's Intrinsic Support for Its Construction of Database

DatCard's sole reference to the specification is to the production history database. (Opp. Brief, p. 10) DatCard contends that PacsGear's construction is wrong because this audit database (i) stores text and (ii) the specification does not state that it is searchable.[3] (DC Opp. p. 10). This argument actually supports PacsGear's proposed definition. Yes, the audit database stores text data. But the specification does not state or in any way imply that the audit database stores images. It cannot be the "database" in the '164 or the '174 or either of the two databases in the '597, because they must be confined to data in DICOM format.

III. THE MEANING OF "AUTOMATICALLY" IS DETERMINED BY THE CLAIMS AND THE SPECIFICATION

"Automatically" is a term with any number of meanings. In the specification, it is implicitly limited, by example - "without prompting for user selection" (Ex. 265, col. 7, ll. 53-55 and "without asking for user direction" (Ex. 265, col. 8, ll. 48-49) to mean that a volitional act of the user is required to accomplish the task. DatCard does not address this but instead cites to an unrelated patent in an unrelated case as extrinsic evidence of how the term should be construed here

DatCard contends that as long as the machine selects images and burns them onto the CD, it does not matter if the user takes any other intervening steps. If DatCard's broad definition were adopted, at least one other prior art reference discussed in Pacsgear's invalidity motion would anticipate the '164, '174 and '597 claims.

Heartlab's DICOMView system allows the user to search a database once for selected images, and conduct another search for additional images for the same

[3] An "audit" database as the name dictates is searchable.

patient, and then send both the originally selected images and the subsequent related images to a CD recorder to be burned with viewing software - with some mouse clicks in between to accomplish it. (Petrocelli Dep. Ex. M – Opp. Pp. 35, 40-41, 50-51, 87-88, Ex. 202 DICOMView User's Manual, pp. 14 and 17-25, 36, 44-45).

IV. THE PATENTS DO NOT ENABLE SEARCHING/BURNING TEXT REPORTS

DatCard here argues that the patent specification enables one of skill in the art to search for and burn text reports – even though it NEVER mentions text reports. (DC Brief pp.5-7). Yet, it contends that the Ratib Article, which actually discusses searching for and burning text reports on the CD and explains how they would need to be converted into order to accomplish it would not have been enough to teach one skilled in the art how to do it. (Dkt.90, pp.9-10). Clearly if the Ratib Article is not enabling than the patent is not.

A. The MediaWriter Cannot Search The Hard Drive For Text Reports, Because It Is Not Searchable.

DatCard contends that the MediaWriter searches the workstation's hard drive for image studies (Dkt. 65:1-10) Dr. Rowberg testified to the contrary that the buffer location on the MediaWriter hard drive is not searchable and in any event, is not the same "database" as the folder storing HL7 reports.

Dr. Rowberg: "That really isn't searching. That's just receiving them. It knows where they are, it doesn't have to search for them…" (Ex. J - Opp. Rowberg Dep. 74:12-75:12)

"Q. Based on your understanding, then, the two databases that are on the outside of the MediaWriter, the second PACS and the Mitra broker, and then the HL7 report database is on the local hard drive, correct?

A. I believe so.

Q. Okay. And then the fourth separate database is the local hard drive where the images are stored.

A. That's the fourth database, yes."

(Ex. J - Rowberg Dep. p. 172:2-11)

V. PRINTING AND AFFIXING A LABEL ARE TWO SEPARATE LIMITATIONS WHICH THE MEDIAWRITER DOES NOT INFRINGE

Claims 16 and 21 include the following two limitations:

> [7] printing a label using the production station, wherein the label includes identifying information associated with the selected medical image data; and
>
> [8] affixing the label to the data storage device using the production station.

DatCard argues that PacsGear's construction is incorrect because PacsGear tries to put these two steps in a specific order. That is not true – PacsGear simply points out that they are <u>two</u> <u>separate</u> steps. DatCard contends that the Media Writer satisfies the "printing the label" limitation by activating "the inkjet head" based solely on Rowberg's testimony (DatCard Brief, p. 23).

DatCard claims that Dr. Rowberg's testimony is (i) entitled to little weight and should be ignored (DC Brief pages 8:24-9:9, 17:10-15, 22:1-3) and (ii) that the Court should deny PacsGear's motions for summary judgment solely based on it. DC Brief pages 8:24-9:9, 17:10-15, 22:1. It is literally not on the same page with itself: On page 22 of its brief after stating that Dr. Rowberg's testimony regarding the meaning of "related medical image data" should be ignored, it argues that his testimony alone, which is based on his faulty claim construction, creates a triable issue of fact. (Opp. Brief, p. 22)

Activating an "ink jet head" prints a label no more than turning a printer on prints a document. The MediaWriter does not satisfy the limitations literally or under the Doctrine of Equivalents. Using an ink jet to directly print information on

a CD is a substantially different way of labeling a CD than (1) printing a label and (2) affixing it to a CD.

VI. THE MEDIAWRITER DOESN'T INFRINGE THE SEARCH/BURN PATENTS LITERALLY OR UNDER THE DOCTRINE OF EQUIVALENTS

A. The '164 Is Not Infringed.

The MediaWriter does not infringe the independent claims of the'164 Patent. PacsGear's Opening Brief re: Infringement (Dkt.69, pp.11-14) and due to similarities with the '174 Patent its Opposition to DatCard's Infringement Claims concerning the '174 Patent. (Dkt.103 pp.4-16), the MediaWriter does not search for "related medical image data" as that phrase is construed by DatCard's expert. All image data retrieved by the MediaWriter is selected image data. Text reports retrieved by the MediaWriter are selected, are not "medical image data" and are not found in the database (the PACS image database). The MediaWriter also does not include a plurality of browsing terminals.

B. '597 Patent is Not Infringed

Pacsgear's Opening Brief clearly explains why the MediaWriter doesn't infringe the '597 Patent when claims are properly construed. DatCard's sound bite from Dr. Horii's testimony regarding medical data is meaningless as it did not refer to the patent specification. It was also selective and misleading.[4]

Claim 1:

The MediaWriter does not perform an automatic search – all images must be selected by the user. "Related medical data" refers only to image data. All image

[4] Q. So if somebody showed you an image and asked you whether this was medical data, you wouldn't know?
A. I wouldn't know. I would need more definition of what their scope of medical data is. *Horii Dep., p.189:10:16*

data retrieved by the MediaWriter is selected image data. The MediaWriter does not perform an automatic search for "medical data", nor does it search for "medical data" in a second database. Text reports retrieved by the MediaWriter are selected and are not "medical data" and are not selected automatically.

Claim 6:

The MediaWriter does not have a second database for "medical data". "Related medical data" refers only to image data. The MediaWriter does not retrieve any additional medical data based on a user's request - all image data retrieved by the MediaWriter is selected image data. The MediaWriter does not search for "medical data" in a second database and its application server is not coupled to such database. Text reports retrieved by the MediaWriter are selected following a series of steps and are not "medical data".

C. The '174 Patent Is Not Infringed

The MediaWriter does not search for "related data", which necessarily means related medical image data in DICOM format. Text reports retrieved by the MediaWriter are selected, are not "related data" and are not found in the database (the PACS image database). Furthermore, the MediaWriter does not perform an automatic search – all images and text reports must be selected by the user, following a series of steps. The MediaWriter also does not include a plurality of browsing terminals. (See also Dkt. 103, pp.1-16)

D. There Are No Genuine Issues Of Equivalence

Each of the above differences between the MediaWriter and the claim limitations are substantial. See Ex. B, Horii Report, pp.10-26 Moreover, any attempt to expand the claim would be thwarted because of the proximity of the prior art. For example, if users were allowed to intervene in connection with the search for related medical images (i.e., it didn't "automatically" occur) then the Heartlab system would anticipate the independent claims. Similarly if related data includes text reports then the Ratib/UCLA System would anticipate the claims in the '597.

CONCLUSION

The MediaWriter does not infringe the search/burn patent, either literally or under the Doctrine of Equivalents.

Dated: January 30, 2012

Willmore F. Holbrow III

Willmore F. Holbrow, III
Dennis G. Martin
BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN, LLP
Attorneys for Defendant PACSGEAR, INC.

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Supported Devices I Conformance Statement

Technical Specifications

Conformance Statements

DICOM
PACS Broker is fully compliant with the Digital Imaging and Communications in Medicine (DICOM) standard. To view the conformance statement in PDF format, **click here**.

HL7
The HL7 Interface Specification provides a set of baseline requirements for a Hospital Information System to communicate with PACS Broker product via the Health Level Seven (HL7) Standard. To view the conformance statement in PDF format, **click here**.

Supported Devices

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EXHIBIT 2

Mitra

Imaging Incorporated

Conformance Statement

PACS Broker 1.5.2

Document: D251-03 Revision: 4.7

Document Status: Approved

EXHIBIT 3

1. Introduction

1.1. Purpose of this Document

This document is a provisional DICOM Conformance Statement for the software product *Broker*.

Broker is a service class provider for DIMSE-N services relating to access to Hospital Information Systems (HIS) and Radiology Information Systems (RIS). *Broker* is intended for use with a wide range of HIS/RIS technologies. Actual combinations for *Broker* plus HIS/RIS may be subject to restrictions not noted in this conformance statement. (For example, some combinations may support certain functions or attributes, and some may not.) Unless otherwise stated, all features conform to the DICOM V3.0 specification; all mandatory elements are supported.

Where the HIS/RIS functions as a service class provider of DIMSE-N services as described above, Broker can be configured to function as a service class user and/or service class provider of these services.

1.2. Sources for this Document

- ACR-NEMA Digital Imaging and Communications in Medicine (DICOM) v3.0, Final Text, 1996.
- Health Level Seven Version 2.1 (HL7 V2.1), 1991.

1.3. Acronyms and Abbreviations

The following acronyms and abbreviations are used in this document.

- ACR American College of Radiology
- ANSI American National Standards Institute
- DICOM Digital Imaging and Communications in Medicine
- DIMSE DICOM Message Service Element
- DIMSE-C DICOM Message Service Element-Composite
- DIMSE-N DICOM Message Service Element-Normalized
- NEMA National Electrical Manufacturers Association
- PDU Protocol Data Unit
- SCP Service Class Provider
- SCU Service Class User
- SOP Service Object Pair
- TCP/IP Transmission Control Protocol/Internet Protocol
- UID Unique Identifier

EXHIBIT 3

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

DATCARD SYSTEMS, INC., a California corporation, Plaintiff, v. PACSGEAR, INC., a California corporation, Defendant.	) Case No.) SACV10-1288 DOC(VBKx)
PACSGEAR, INC., a California corporation, Counter-Claimant, v. DATCARD SYSTEMS, INC., a California corporation, Counter-Defendant.	)

CONFIDENTIAL - ATTORNEY'S EYES ONLY

VIDEOTAPED DEPOSITION OF 30(b)(6) witness, BRIAN CAVANAUGH, taken on behalf of Plaintiff, at Knobbe Martens Olson & Bear, LLP, 333 Bush Street, 21st Floor, San Francisco, California, commencing at 9:06 a.m., Tuesday, August 16, 2011, before Donna J. Blum, Certified Shorthand Reporter, No. 11133.

EXHIBIT 4

converts the report to an HTML?

09:36 A. That's correct.

09:36 Q. Okay. And then the HTML file can be burned to a disk?

09:36 A. That's correct. I'm confused about the MediaWriter server versus the MediaWriter product --

09:36 Q. Okay, yeah.

09:36 A. The MediaWriter server itself doesn't talk to HL-7.

09:36 Q. I understand, but the MediaWriter product can receive an HL-7 report, convert it to HTML and convert it to a disk?

09:36 A. Yes.

09:36 Q. Okay. Let's see, I think you'd mentioned HTML, and you mentioned DICOM structured reports.

Does the MediaWriter ever receive reports from a Mitra broker?

09:36 A. The MediaWriter actually queries a Mitra. The Mitra report interface is a query interface. It doesn't broadcast.

09:37 Q. Okay. And does MediaWriter query and retrieve from a Mitra broker radiological reports?

09:37 A. It does.

09:37 MR. HOLBROW: I'm going to -- are you talking about hypothetical MediaWriters or --

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

HONORABLE MARIANA R. PFAELZER, JUDGE PRESIDING

DATCARD SYSTEM, INC.,)
)
)
)
Plaintiff,)
)No. 10-1288MRP
VS)
)
PACSGEAR, INC.,)
)
)
Defendant.)
______________________________________)

Reporter's Transcript of Proceedings
MARKMAN RE-HEARING
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Los Angeles, California
MONDAY, NOVEMBER 5, 2012

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Federal Official Court Reporter
312 North Spring Street, Room 432
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Telephone: (213) 894-2969
annekielwasser@gmail.com
AKtranscripts.com

image."

THE COURT: I think probably should.

What page are you on?

MR. HOLBROW: That's page 34, Your Honor.

THE COURT: Okay. Please.

MR. HOLBROW: Okay. And we understand the Order with respect to the evidence, and we'll just maintain our evidentiary objection. Thank you.

THE COURT: Please.

MR. SUMMERS: Your Honor, may I approach?

THE COURT: Certainly. Thank you.

Now, I'm going to expect you to start with *search and burn*.

MR. SUMMERS: Yes, Your Honor.

THE COURT: All right.

MR SUMMERS: Before I begin, I would just like to say a little bit about DICOM. It is a way to communicate between two entities, a PACS database, for example, and the MediaWriter. As you know, DICOM stands for digital imaging and communications in medicine, and it's a stand for the handling and transmitting of information in medical imaging.

THE COURT: Yes, I know that.

MR. SUMMERS: Includes file formats, definitions and so forth. And DICOM -- things that are formatted in DICOM are generally called objects, and they can be images,

but they can also be things that are not images, like structured reports, Mitra broker reports. Because for these diagnostic reports to be sent from one database to the MediaWriter, they come across in a DICOM format, And they're not images in the strictest sense. They are wrapped in a DICOM format which is, itself, sometimes called an image in the terminology, but it's not like a scan of my brain. But it comes across in what's called the DICOM format, which is considered an object, some people consider it to be an image; but it's not the image in the sense that the patent is talking about when we talk about CT scans and things like that.

So, I'm going to try to get through this quickly, Your Honor. We have the handout for you. It's another PowerPoint presentation, which I've printed in black and white, so it's easier for you to make notes if you'd like.

Page 2 of that handout lists the outline for today's hearing. I think we've already agreed to that. And I won't dwell on that.

Turning to page 4, Your Honor, is the overview of the first motion. I'm going to talk about the '174 patent. It just reminds the Court what we said last time: What claims are asserted, what the accused product is, and how we assert that PacsGear is a contributory infringer

and the direct infringers of the customers.

Page 5 is directed to some of the points I've been making already. It's our view that radiologists' reports are formatted in the standard medical imaging format. And under the Court's construction, we view related data as excluding these kinds of text reports unless they're stored in a standard medical imaging format.

PacsGear is searched that these reports are in a text format and not considered DICOM images, and we disagree. And this is set forth in some of the slides that I'm going to discuss now. It shows that diagnostic reports are formatted in a standard medical imaging format, just like DICOM images of your brain or another body part.

Page 6 is a -- this is new evidence, Your Honor, but I'll just point out -- it's a deposition of PacsGear 30(b)(6) witnesses. And they were asked: Does MediaWriter search for Mitra broker radiological reports? And the answer was: Yes, it does.

The next page, page 7, is also part of the additional evidence, and it just shows that Mitra broker uses the DICOM format. We have some excerpts there that discuss Mitra broker reports and how they complied with the DICOM standard.

Page 8 shows the kinds of databases that are typically set up when the MediaWriter is used. The box on

the left shows a situation where there are two distinct databases, a Mitra broker database to the left, a PACS database to the right, and then an MediaWriter below it. All those facilities or databases communicate with each other in the DICOM format. That's how they're set up.

The box on the right shows a situation where the PACS and the Mitra broker reports are in the same database. That's important for the '174 patent. And that database can communicate with the MediaWriter via DICOM. And the support for -- of Mitra broker being in the same box or database as a PACS is cited there in Exhibit 4 from that -- from the Smith declaration with some additional testimony from PacsGear's 30(b)(6) witness.

If we could turn to slide 10 -- strike that, Your Honor. Let's skip some of this and get through this quickly.

Let's turn to slide 12, if you would. After the MediaWriter is turned on and the administrator logs in, a screen is displayed. And that's shown on page 12. What I'm going to talk about now is what an administrator does to -- when they purchase the MediaWriter, they have to do a setup, and this is how they set it up to automatically search for reports, the related data.

THE COURT: Now, you're going to talk to me about infringement, are you?

further from DatCard, Your Honor.

THE COURT: All right.

And from you?

MR. HOLBROW: No, Your Honor. I think --

THE COURT: All right. Then, let me finish this off by reading you one part of the *claim construction* Order. I think I have it here: It's on page 10. The part of it that, perhaps, you, from the plaintiff's standpoint, didn't quite understand is the part that -- begins on page 10 -- that begins: "Under the Court's construction, the answer depends on whether the reports are formatted in the standard medical imaging format. PacsGear asserts that such reports are not in a standard medical imaging format. The radiology reports are in text format. DatCard does not appear to take a contrary position. Related image data does not cover such reports assuming that they're not formatted in standard medical imaging format."

Now, the "assuming" part of that makes the rest of it, according to what you said, ambiguous. Is that right?

MR. SUMMERS: Let me see if I can respond to that. The part that says DatCard doesn't appear to take a contrary position. We do take a contrary position.

THE COURT: I know you do.

MR. SUMMERS: So, I'm not sure -- I want to make

sure I answer your question.

THE COURT: The last part of it made you think that we agreed with you that reports were included, medical reports.

MR. SUMMERS: The way I read that --

THE COURT: If they had been formatted properly.

MR. SUMMERS: Assuming that they are -- I guess I would say assuming they are formatted in the standard medical imaging format --

THE COURT: Then there is no problem at all.

MR. SUMMERS: Yeah, then they are covered.

THE COURT: Yes, but they're covered anyway.

MR. SUMMERS: I'm not sure I follow.

THE COURT: Well, did you -- let me put the question to you directly. When you read the *claim construction*, did you believe -- did you feel prior to the argument that the *claim construction* says that reports are included?

MR. SUMMERS: If recorded in the standard medical imaging format.

THE COURT: Ah, yes, yes. Well, it doesn't say that quite. And perhaps you'd like to make it just a little clearer.

MR. SUMMERS: I think that would be helpful.

THE COURT: All right.

MR. SUMMERS: Because that's what we assume. We assume that if a diagnostic report was wrapped in the DICOM format in a standard medical imaging format, we would -- we were -- it was within the scope of the claim.

THE COURT: Yes, yes.

MR. SUMMERS: And you're telling me that we are wrong about that.

THE COURT: Right.

MR. SUMMERS: Clarification on that would be appreciated, Your Honor.

THE COURT: And I understand your argument.

MR. SUMMERS: Thank you.

THE COURT: Thank you, both.

MR. HOLBROW: Thank you, Your Honor.

THE COURT: All right.

MR. HOLBROW: There was just one brief -- trial date. I think it's currently set for December 10.

THE COURT: Oh, well, you're not -- you can get a trial. Judge Carter had criminal cases, and we can try this whenever you want to.

MR. HOLBROW: Never would be the preference.

THE COURT: I know. We're not going to pick a date.

MR. HOLBROW: It was --

MR. SUMMERS: I think I assumed, maybe

Link: 57

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

DATCARD SYSTEMS, INC., a California corporation, Plaintiff, v. PACSGEAR, INC., a California corporation, Defendant.	Case No. 8:10-cv-01288-MRP **Order Denying DatCard's Motion to Preclude the Expert Opinion Testimony of Steven Horii and Ian Jestice on Obviousness**

I. Introduction

DatCard Systems, Inc. ("DatCard") has sued PacsGear, Inc. ("PacsGear") for infringing its patents, all of which generally relate to the handling and delivery of medical images. PacsGear's experts, Dr. Steven Horii and Ian Jestice, have prepared expert reports concluding that DatCard's patents are obvious in light of the prior art. DatCard claims that these reports fail to comply with Rule 26(a)(2)(B) because they (1) lack an element-by-element comparison of the claims

of each patent to the prior art, and (2) fail to provide evidence or analysis of why a person having ordinary skill in the art would have combined the prior art elements to arrive at the claimed inventions. The Court denies DatCard's motion.

II. Legal Principles of the Adequacy of Expert Reports

Barring a stipulation or court order to the contrary, Federal Rule of Civil Procedure 26(a)(2)(B) requires expert reports to contain "a complete statement of all opinions the witness will express and the basis and reasons for them . . . [and] the facts or data considered by the witness in forming them . . . ." FED.R.CIV.P. 26(a)(2)(B). "Rule 37(c)(1) gives teeth to these requirements by forbidding the use at trial of any information required to be disclosed by Rule 26(a) that is not properly disclosed." *Yeti by Molly, Ltd. v. Deckers Outdoor Corp.*, 259 F.3d 1101, 1106 (9th Cir. 2001).

Two Federal Circuit cases serve as guideposts for determining the Rule 26 compliance of expert reports pertaining to patent obviousness: (A) *Innogenetics v. Abbott Labs.*, 512 F.3d 1363 (Fed. Cir. 2008) (expert report found inadequate); and (B) *Meyer Intellectual Properties Ltd. v. Bodum, Inc.*, 690 F.3d 1354 (Fed. Cir. 2012) (expert report found adequate).

A. Innogenetics (Expert Report Found Inadequate)

The *Innogenetics* expert with over 17 years of experience in molecular virology, Dr. Bruce Patterson, merely listed a number of prior art references and

then concluded with the stock phrase "to one skilled in the art it would have been obvious to perform the genotyping method in [claims 1-9 & 12-13] of the '704 patent [the patent-in-suit]." 512 F.3d at 1373. Nowhere did Dr. Patterson state how or why a person ordinarily skilled in the art would have found the claims of the '704 patent obvious. *Id.* The Federal Circuit found that the district court did not err in finding Dr. Patterson's expert report deficient under Rule 26. "Such vague testimony," the Federal Circuit found, "would not have been helpful to a lay jury in avoiding the pitfalls of hindsight that belie a determination of obviousness." *Id.* "[T]here must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *Id.*

B. Meyer (Expert Report Found Adequate)

In *Meyer*, the Federal Circuit reiterated the inadequacy of *Innogenetics*-type reports, "In the patent context, an expert report that merely lists a number of prior art references and concludes that one skilled in the art would find the claims obvious is deficient under Rule 26." 690 F.3d at 1375. But unlike the deficient *Innogenetics* report, the *Meyer* report passed the adequacy test because Robert John Anders, the *Meyer* expert and an industrial designer with 50 years of experience, did "more than merely list prior art references and provide a conclusion of obviousness." *Id.* at 1375.

> Careful review of Anders' report reveals that it contains a sufficiently detailed statement of his opinions and the bases for his conclusions. ***This is***

> ***particularly true given that the technology involved in this case—using a plunger to froth milk in a container—is not complex.*** According to Anders, the patents-in-suit are obvious because one skilled in the art would have been motivated based on familiarity with the prior art to combine the known method for aerating milk in a frother with the structure of a French press. ***In other words, Anders invoked the common sense of one skilled in the art as evidence of motivation to combine prior art references. Given the technology involved, we find no fault in Anders' reliance on common sense in rendering his obviousness opinion. Indeed, this court has specifically recognized that the common sense of one skilled in the art can play a role in the obviousness analysis.*** *See Perfect Web Techs., Inc. v. InfoUSA, Inc.,* 587 F.3d 1324, 1329 (Fed.Cir.2009) (holding that "an analysis of obviousness ... may include recourse to logic, judgment, and common sense available to the person of ordinary skill [which] do[es] not necessarily require explication in any reference or expert opinion").
>
> ***Because the technology involved is simple and common sense would motivate one of skill in the art to make the combination, Anders' report is sufficiently detailed.*** Accordingly, we conclude that the district court abused its discretion when it excluded Anders' testimony. We further find that the exclusion of Anders' testimony was not harmless because it impaired Bodum's ability to present its obviousness defense. And, as Bodum points out in its brief, while Meyer's expert was permitted to testify as to why the patent was not obvious, the exclusion of Anders' testimony made it look as though Bodum had no rebuttal.

Id. at 1375-76 (emphasis added).

The inadequate *Innogenetics* report, authored by Dr. Bruce Patterson, is quite similar to the adequate *Meyer* report, authored by Robert John Anders. In fact, the only significant difference between the two reports is that Anders (in *Meyer*) cited common sense as the reason to combine prior art references to arrive at the invention – using a plunger to froth milk in a container – whereas Patterson (in *Innogenetics*) simply listed prior art references followed by the stock phrase "to

one skilled in the art it would have been obvious to perform the genotyping method in [claims 1-9 & 12-13] of the ‘704 patent [the patent-in-suit].” 512 F.3d at 1373.

To be sure, the Federal Circuit noted the presence of “detailed claim charts” in *Meyer* in its assessment of the adequacy of Anders’ expert report. *Id.* at 1375. But the presence of claim charts did not render the Anders expert report compliant with Rule 26. Had Anders submitted detailed claim charts but not cited common sense as the basis for his obviousness conclusion, or had the technology been complex, that could well have rendered the Anders report non-compliant, notwithstanding detailed claim charts.

Conversely, had Dr. Patterson in *Innogenetics* included “detailed claim charts,” his report would almost certainly have still failed to pass muster under Rule 26. Its fatal defect was the repeated and formulaic invocation of the stock phrase, “to one skilled in the art it would have been obvious to perform the genotyping method in [claims 1-9 & 12-13] of the ‘704 patent [the patent-in-suit].” 512 F.3d at 1373. Put another way, claim charts do not explain the disparate appellate fates of the Anders and Patterson reports in *Meyer* and *Innogenetics* respectively.

Then why did the decision to exclude one report survive appeal when another did not? What explains the discrepancy? Two differences are immediately apparent: (1) Anders (in *Meyer*) cited common sense as the basis for the obviousness conclusion whereas Patterson (in *Innogenetics*) featured a conclusory

stock phrase; and (2) *Meyer* involved simple technology (using a plunger to froth milk in a container) whereas *Innogenetics* involved complex technology (genotyping). The recitation of common sense *in haec verba* in an expert report cannot, under any reasonable regime, transform an otherwise deficient expert report into a compliant version. The explanation must be that the bar for Rule 26 compliance for expert reports on patent obviousness is *lower* for simple-technology patents than for complex-technology patents. The bolded portions in the *Meyer* excerpt confirm the Federal Circuit's recognition of this correlation. The simpler the patented technology, the lower the bar for an expert report to fall into compliance with Rule 26, and the less problematic an expert's citation of common sense to reach a conclusion of obviousness.

The bar for Rule 26 compliance of expert reports on obviousness in patent cases must, as a matter of logic, be at least as flexible as obviousness jurisprudence itself. Requiring arbitrary levels of granularity with respect to claim charts and asking experts to *say more* where not much more needs to be said, given the simplicity of an invention, is not consistent with the flexibility of obviousness jurisprudence under *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007). That said, the Court is mindful of the perils of hindsight bias, a potent threat that district courts must always be mindful of when analyzing the obviousness of simple technologies, particularly where the analysis takes place a decade or more after the critical date.

> Indeed, where the invention is less technologically complex, the need for *Graham* findings can be important to ward against falling into the forbidden use of hindsight. Simply because the technology can be easily understood does not mean that it will satisfy the legal standard of obviousness. In fact, objective consideration of simple technology is often the most difficult because, once the problem and solution appear together in the patent disclosure, the advance seems self-evident. Instead, the proper analysis requires a form of amnesia that "forgets" the invention and analyzes the prior art and understanding of the problem at the date of invention.
>
> *Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1379 (Fed. Cir. 2012)

On the one hand, the bar for Rule 26 compliance is lower for expert reports on obviousness of patent claims covering simple technology. On the other, hindsight is problematic for presumptively-valid patents covering simple technology. The correct resolution must achieve two goals: (1) preserve recourse to common sense under *KSR* by entering into evidence expert reports citing common sense in simple-technology cases; and (2) curbing hindsight bias via limiting instructions to the jury (in case of a jury trial) and by assessing (as the Federal Circuit now *requires* in each instance) secondary considerations of non-obviousness.

III. Application

The application of the above legal principles to the matter at hand is trivial. The Court finds that the patents-in-suit do not involve complex technology. As such, the expert reports of Dr. Horii and Mr. Jestice comply with Rule 26 by analogy to *Meyer* because both reports list prior art references and cite common sense – an approach which suffices for simple-technology patents such as the ones in suit.

A. Dr. Horii's Report Cites Common Sense

In his expert report, Dr. Horii's states, in relevant part:

> My takeaway from *KSR* is that, while there are a number of factors that should be considered, that one should not treat them as a rigid checklist. The passage in *KSR* that is most useful, at least to me, are these:
>
> > "When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103."
>
> More succinctly:
>
> > "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results."
>
> It is my understanding that it is acceptable to combine prior art references if the references themselves provide a suggestion, motivation or reason to combine or if the link between the references is simple common sense.
>
> Dr. Horii's report at 16.

B. Mr. Jestice's Report Cites Common Sense

In his expert report, Mr. Jestice states, in relevant part, "Sometimes the prior art references themselves may provide a suggestion, motivation, or reason to combine, but other times the nexus of linking two or more prior art references is ***simple common sense***." Mr. Jestice's report at 8. The expert reports' failure to include detailed claim charts is not by itself fatal under Rule 26 for the aforementioned

reasons. *Supra* at 5-6 (explaining the role of the level of detail of claim charts in assessing the adequacy of an expert report on patent obviousness under Rule 26).

To be sure, the Court's characterization of the patents-in-suit as "simple" is hardly a clue regarding its opinion regarding their validity under, for example, Section 103. Patent law lacks a doctrine of simplicity. To be sure, as a matter of logic, technically simple patents are perhaps more vulnerable to obviousness-based invalidity than technically complex patents. But they are not obvious *because* they are technically simple. Obviousness is, in large part, a function of the extent of the disclosure in the corpus of prior art. Indeed, technically involved patent claims are often obvious in light of the prior art. And technically trivial patents are often non-obvious in light of the prior art. The intellectual property regime is somewhat agnostic to scientific complexity because the system is in place to incentivize *innovation* – not untangling *complexity in and of itself*.[1]

Were Dr. Horii and Mr. Jestice testifying on genotyping, perhaps their reports might have failed to pass muster under Rule 26. But they are not. They are

[1] Indeed, theoretical mathematicians and physicists have little to gain from 35 U.S.C. § 154(a)(1) ("Every patent shall . . . grant to the patentee . . . the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States . . . ."). The allure of money might mean little to the incentives of those most interested in solving complex theoretical problems. *See, e.g.*, B. Forrest, *Searching for Grigori Perelman, Russia's Reclusive Maths Genius*, available at http://www.telegraph.co.uk/culture/9475585/Searching-for-Grigori-Perelman-Russias-reclusive-maths-genius.html (last accessed on February 15, 2013); *but see* Math Bounties: Will Cash Prizes Help in the Quest to Solve the World's Hardest Math Problems?, available at http://acfnewsource.org.s60463.gridserver.com/science/math_bounties.html (last accessed on February 15, 2013). Other incentive systems, such as fame, recognition, legacy, etc., might be more appropriate for basic research. *But see* Feynman: I Don't Like Honors, available at http://www.youtube.com/watch?v=f61KMw5zVhg (last accessed on February 15, 2013).

testifying about a technically simple invention. As such, their reports and the accompanying citation of common sense render their reports adequate under Rule 26. Again, the Court has expressed no position about the weight of the evidence furthered by PacsGear's experts – it only finds that they comply with Rule 26.

IV. CONCLUSION

DatCard's motion to preclude the expert opinion testimony of Steven Horii and Ian Jestice regarding obviousness of the asserted patents is denied. IT IS SO ORDERED.

DATED: March 12, 2013

Mariana R. Pfaelzer

Hon. Mariana R. Pfaelzer
United States District Judge

Link: 60

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

DATCARD SYSTEMS, INC., a California corporation, Plaintiff, v. PACSGEAR, INC., a California corporation, Defendant.	Case No. 8:10-cv-01288-MRP-VBK **Order Re DatCard Systems, Inc.'s Motion for Summary Judgment that U.S. Patent Nos. 7,302,164, 7,783,174, 7,729,597 and 7,734,157 are not Invalid Under 35 U.S.C. § 102**

I. Introduction

DatCard Systems, Inc. ("DatCard") has sued PacsGear, Inc. ("PacsGear") for infringement of U.S. Patents Nos. 7,302,164 ("the '164 patent"), 7,783,174 ("the '174 patent"), 7,729,597 ("the '597 patent"), and 7,734,157 ("the '157 patent"). PacsGear has raised an affirmative defense that the above patents are invalid as anticipated under 35 U.S.C. § 102. ECF No. 36-1 at ¶¶ 40-43. DatCard moves for

summary judgment that the above patents "are not invalid under 35 U.S.C. § 102." ECF No. 60 at 1.

II. Legal Principles

The Court shall grant summary judgment if: (1) the movant shows that there is no genuine dispute as to any material fact; and (2) the movant is entitled to judgment as a matter of law. FED.R.CIV.P. 56(c); *see Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986). The Court must: (1) identify material facts by reference to the governing substantive law, Anderson, 477 U.S. at 248; (2) disregard irrelevant or unnecessary factual disputes, id.; and (3) view facts and draw reasonable inferences in favor of the nonmoving party, *Scott v. Harris*, 550 U.S. 372 (2007).

To anticipate under 35 U.S.C. § 102, a prior art reference must disclose each and every limitation of the claimed invention, must be enabling, and must describe the claimed invention sufficiently to have placed it in possession of a person of ordinary skill in the field of the invention. See *Helifix Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 1346 (Fed. Cir. 2000). Anticipation "requires identity of invention: the claimed invention, as described in appropriately construed claims, must be the same as that of the reference, in order to anticipate." *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply, Inc.*, 45 F.3d 1550, 1554 (Fed. Cir. 1995). Each limitation must be expressly or inherently described in a single prior art reference

for that reference to be anticipating. *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed. Cir. 2002). Inherent anticipation requires that undisclosed limitations are necessarily – not merely probably or presumably – present in the prior art. *Id.* at 1295.

"If the movant does not bear the burden of proof, then he can obtain summary judgment simply by showing the nonexistence of any essential element of the opposing party's claim or affirmative defense." Martin B. Louis, *Federal Summary Judgment Doctrine: A Critical Analysis*, 83 Yale L.J. 745, 747 (1974). Under § 282 of the Patent Act of 1952, "[a] patent shall be presumed valid" and "[t]he burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." 35 U.S.C. § 282. The Supreme Court has held that § 282 requires an invalidity defense such as anticipation under 35 U.S.C. § 102 to be proved by clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. Partnership*, 131 S.Ct. 2238, 2242 (2011).

Consequently, a patentee can obtain summary judgment that a patent is not invalid under § 102 "simply by showing the nonexistence of any essential element" of the accused infringer's affirmative defense of anticipation. Louis at 747. Anticipation requires an express or inherent disclosure of each claim element *in a single prior art reference*. As such, to the extent the Court rules in favor of a

patentee moving for summary judgment of no anticipation, any such judgment of non-anticipation would be limited to specific prior art references.[1]

III. Discussion

The Court finds that Mehta does not anticipate Claims 9 and 15 of the ‘164 patent and Claim 1 and 8 of the ‘174 patent because it lacks disclosure, both express and inherent, of related data or related medical image data. Consequently, the Court grants DatCard’s motion for summary judgment that the above claims are not invalid as anticipated by the Mehta reference.

Claims 9 and 15 of the ‘164 patent require “a search module configured to search the database for ***related medical image data*** that is related to the selected medical image data,” ‘164 at 1:35-37 (reexamination certificate); “a production station that is configured to record . . . the selected medical image data . . . [and] the ***related medical image data***,” *id* at 1:38, 46; and “a viewing program . . . configured to allow viewing of the selected and the ***related medical image data***.” *Id.* at 1:45-46. Claim 1 of the ‘174 patent requires “a search module configured to automatically search the database for ***related data based on the user selection***” and “a production station . . . configured to record . . . the selected medical image data .

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[1] Issued patents enjoy a presumption of validity vis-à-vis all prior art, i.e., a blanket presumption of validity. One aspect of validity is novelty. Thus, issued patents enjoy a blanket presumption of novelty, i.e., non-anticipation, vis-à-vis the universe of prior art references. To the extent DatCard seeks to transform the blanket presumption of novelty which it already enjoys into a corresponding blanket *judgment* of novelty, the Court cannot oblige. What the Court *can* grant is a judgment of novelty, i.e., non-anticipation, with respect to one or more named prior art references, e.g., the Mehta reference.

. . [and] ***the related data***.” ‘174 at 9:35-39. Claim 8 of the ‘174 patent requires “automatically searching the database for ***related data*** based on the user selection.” ‘174 at 10:18-19. All of the above claims feature searching for, storing, or viewing not only selected medical image data but also related medical image data or related data. The Court has previously construed that “related medical image data” in the ‘164 patent and “related data” in the ‘174 patent refer to “[d]ata that is: (1) formatted in a standard medical imaging format; and (2) related to the selected medical imaging data.” Cl. Constr. Order at 34 (ECF No. 145).

The Mehta reference lacks an express disclosure for “related medical image data” or “related data” as the Court has construed these terms. Mehta discloses, “Once requested, the operator is responsible for ***selecting the appropriate patient records*** from the department PACS using an image library PC.” Opp. at 7 (citing Mehta, p. 78) (emphasis added). Assuming *arguendo* that Mehta discloses searching for, storing, or viewing data – the phrase “selecting the appropriate patient records” only pertains to *selected* medical image data. No other part of the Mehta reference contains any reference to *related* medical image data or *related* data.

The Mehta reference also lacks an inherent disclosure for “related medical image data” or “related data.” PacsGear argues that the phrase “pertinent imaging studies” in Mehta constitutes an inherent disclosure of related medical image data.

Opp. at 7 (citing the Defendant's Expert, Dr. Horii, as concluding that to one skilled in the art, the Mehta system necessarily has a mechanism for searching for related medical imaging studies).The Court disagrees.

In the "Materials and Methods" section, the Mehta article states, "Once requested, the operator is responsible for selecting the ***appropriate patient records*** from the department PACS using the image library PC. Using custom software, ***these images*** [i.e., "appropriate patient records"] are recorded onto the CD-ROM in standard DICOM format stripped of any institution dependent factors, such as the medical record number. The CD-ROM is ***then provided*** to the patient . . . ." Mehta at 78-79.

In the next section entitled "Results," Mehta continues, "Patients are now able to receive a CD-ROM . . . contain[ing] copies of ***all pertinent imaging studies***." *Id.* In the context of the full excerpt with particular attention to the highlighted phrases, the mere fact that a CD-ROM contains "***all*** pertinent

> Once requested, the operator is responsible for selecting the appropriate patient records from the department PACS using the image library PC. Using custom software, these images are recorded onto the CD-ROM in standard DICOM format stripped of any institution dependent factors, such as the medical record number. This CD-ROM is then provided to the patient or referring physician pending appropriate security protocols are fulfilled, including identification in the case of a patient or consent to acquire studies in that of a physician.
>
> RESULTS
>
> Patients are now able to receive a CD-ROM with copies of their radiologic studies. This CD-ROM contains copies of all pertinent imaging studies for the particular patient, an Internet web browser to view images, and a DICOM-based engine to transfer images to a receiving institutional PACS.

imaging studies" does not necessarily refer to related medical image data. The remainder of the Mehta article lacks any reference to the concept of related images. To be sure, "all" pertinent imaging studies possibly – perhaps even *probably* – includes *related* medical image data given that related images are "pertinent" to a patient. But not *necessarily* so. Again, "[i]nherent anticipation requires that the missing descriptive material is 'necessarily present,' not merely probably or possibly present, in the prior art." *Trintec*, 295 F.3d at 1295.

The Court is not construing the *scope* of "all pertinent imaging studies" as it would during a claim construction proceeding. The Court is identifying the scope of "all pertinent imaging studies" in a narrower sense – limited to what the term literally *and necessarily* includes in the context of the entire Mehta article. For example, in *Trintec*, the Federal Circuit found that the disclosure of a color printer did not inherently disclose the claimed color photocopier. *Id.* This, though "the difference between a printer and a photocopier may be minimal and obvious to those skill in the art. Nevertheless, obviousness is not inherent anticipation." *Id.* at 1296. This shows that inherency is an exacting requirement.

"Whether a claim limitation is inherent in a prior art reference is a question of fact." *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1328 (Fed. Cir. 2001). "[R]ecourse to extrinsic evidence is proper to determine whether a feature, while not explicitly discussed, is necessarily present in a reference." *Id.* at

1328. "The evidence must make clear that the missing feature is ***necessarily*** present, and that it would be so recognized[2] by persons of ordinary skill in the relevant art." *Id.* (emphasis added). PacsGear relies on extrinsic evidence in the form of Dr. Horii's testimony to establish the inherent disclosure of "related medical image data" in the Mehta reference. Dr. Horii testified that Mehta "utilizes a search module that can search the database for selected and related images ***as it calls for collecting 'all pertinent imaging studies for the particular patient.'***" Expert Report of Steven Horii, M.D. at 15 (emphasis added). Dr. Horii's testimony amounts to, as the bolded portion of his expert testimony indicates, a mere citation of the phrase "all pertinent imaging studies." Again, "all pertinent imaging studies" does not necessarily include related medical images or related data.

IV. Conclusion

DatCard does not bear the burden to prove the validity of its patents – they are presumptively valid. PacsGear, on the other hand, bears the burden of proving its affirmative defense of invalidity under § 102 by clear and convincing evidence. By proving that Mehta lacks an express and inherent disclosure of related data or related medical image data, DatCard has established the nonexistence of an essential element of PacsGear's affirmative defense of anticipation with respect to

[2] *Cf.* MEHL/Biophile Intl. Corp. v. Milgraum, 192 F.3d 1362, 1365, 52 USPQ2d 1303, 1305 (Fed.Cir.1999) ("Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art."); Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1946-47 (Fed.Cir.1999) ("Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art.").

the Mehta reference. Consequently, DatCard is entitled to summary judgment that the Mehta reference does not anticipate Claims 9 and 15 of the '164 patent and Claims 1 and 8 of the '174 patent.

Consequently, the Court grants DatCard's motion for summary judgment that Mehta does not anticipate Claims 9 and 15 of the '164 patent and Claim 1 and 8 of the '174 patent. IT IS SO ORDERED.

DATED: March 12, 2013

Mariana R. Pfaelzer

Hon. Mariana R. Pfaelzer
United States District Judge

LINKS: 54, 150

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	10-cv-1288-MRP-VBK	Date	4/1/2013
Title	DatCard Sys., Inc. v. PacsGear Inc.		

Present: The Honorable	**MARIANA R. PFAELZER**

Cynthia Salyer	None	N/A
Deputy Clerk	Court Reporter / Recorder	Tape No.

Attorneys Present for Plaintiff:	Attorneys Present for Defendant:
None	None

Proceedings: **(In Chambers)**

Order Re ECF Nos. 54, 150

DatCard Systems, Inc. ("DatCard") has moved the Court to bifurcate the issue of inequitable conduct for a separate bench trial. ECF No. 54. Separately, DatCard has filed an *ex parte* application for allowing the submission of additional evidence on the pending motions for summary judgment. ECF No. 150.

The Court has already granted Pacsgear's motions for summary judgment of non-infringement as to the Search/Burn patents (U.S. Patent Nos. 7,302,164, 7,729,597, and 7,783,174), ECF No. 68 (order pending), and its motion for summary judgment of invalidity as to the HIPAA and Timeout patents. *See* ECF No. 74 (order pending), No. 160 (finding that the Timeout patent is invalid as obvious). As such, DatCard's motion to bifurcate the issue of inequitable conduct for a separate bench trial is moot.

When deciding the pending summary judgment motions, the Court considered DatCard's additional submissions attached to its *ex parte* application. As such, DatCard's *ex parte* application is likewise moot.

IT IS SO ORDERED.

Case: 13-1445 Document: 28-3 Page: 1208 Filed: 11/08/2013

CERTIFICATE OF SERVICE

I certify that on November 8, 2013, this NONCONFIDENTIAL JOINT APPENDIX [Volume II of II, Pages A1910 – A5776] was filed electronically using the CM/ECF system, which will send notification of such filing to counsel of record for Defendant-Appellee, Pacsgear, Inc., as follows:

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